DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 308, 310, 318, 320, 325, 326, 327, and 381

[Docket No. 93–016P]

RIN 0583–AB69

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing requirements applicable to all FSIS-inspected meat and poultry establishments that are designed to reduce the occurrence and numbers of pathogenic microorganisms in meat and poultry products and to reduce the incidence of foodborne illness associated with the consumption of those products. The proposals would (1) clarify the responsibility of establishment management to ensure compliance with sanitation requirements; (2) require at least one antimicrobial treatment during the slaughter process prior to chilling of the carcass; (3) establish enforceable requirements for prompt chilling of carcasses and parts; (4) establish interim targets for pathogen reduction and mandate daily microbial testing in slaughter establishments to determine whether targets are being met or remedial measures are necessary; and (5) require that all meat and poultry establishments develop, adopt, and implement a system of preventive controls designed to improve the safety of their products, known as HACCP (Hazard Analysis and Critical Control Points). FSIS is also announcing its intent to initiate rulemaking jointly with the Food and Drug Administration (FDA) to establish Federal standards for the safe handling of food during transportation, distribution, and storage of the products prior to delivery to retail stores, as well as further efforts to encourage adoption and enforcement by States of consistent, science-based standards to ensure food safety at the retail level. These proposals and initiatives are part of a comprehensive strategy to improve the safety of meat and poultry products when they are delivered to the consumer.

DATES: Comments must be received on or before June 5, 1995.

ADDRESSES: Submit written comments in triplicate to Diane Moore, Docket Clerk, Room 3171 South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments, as permitted under the Poultry Products Inspection Act, should be directed to the appropriate person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: (1) GENERAL: Dr. Judith A. Segal, Director, Policy, Evaluation, and Planning Staff, (202) 720–7773; (2) SANITATION: Dr. Isabel Arrington, Staff Officer, Inspection Management Program, Inspection Operations, (202) 720–7905; (3) ANTIMICROBIAL TREATMENTS: Dr. William O. James, II, Director, Slaughter Inspection Standards and Procedures Division, Science and Technology, (202) 720–3219; (4) TEMPERATURE CONTROLS: Carl S. Custer, Staff Officer, Processed Products Inspection Division, Science and Technology, (202) 501–7321; (5) MICROBIAL TESTING: Dr. Richard A. Carnevale, Assistant Deputy Administrator, Scientific Support, Science and Technology, (202) 205–0675; (6) HACCP: Dr. Dorothy Stringfellow, Director, HACCP Office, Science and Technology, (202) 690–2087; (7) TRANSPORTATION AND RETAIL: Patrick J. Clerkin, Director, Evaluation and Enforcement Division, Compliance Program, Regulatory Programs, (202) 254–2537, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

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SUPPLEMENTARY INFORMATION:

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I. Background

Purpose of This Document

The mission of the Food Safety and Inspection Service (FSIS) is to ensure that meat and poultry products are safe, wholesome, and accurately labeled. Current FSIS regulatory requirements and inspection procedures contribute much to the achievement of these goals, but there is a critical gap in the FSIS program. The current program does not directly target pathogenic microorganisms, which frequently contaminate otherwise wholesome carcasses. It also does not make meat and poultry establishments legally responsible for taking systematic, preventive measures to reduce or eliminate the presence of pathogenic microorganisms in meat and poultry products. This gap in the FSIS program has important public health implications because a significant portion of the cases of foodborne illness in the United States is associated with the consumption of meat and poultry products that are contaminated with pathogenic microorganisms.

To protect public health and reduce the risk of foodborne illness, FSIS proposes to fill the gap in its current system by requiring new measures that will target and reduce the presence of pathogenic microorganisms in meat and poultry products. FSIS is also beginning a fundamental shift in the paradigm governing its inspection program. FSIS

will begin to build the principle of prevention into its inspection program by requiring all meat and poultry establishments to adopt the Hazard Analysis and Critical Control Point (HACCP) approach to producing safe meat and poultry products. FSIS will also take steps to encourage preventive measures on the farm, require preventive controls during transportation, and support State-based HACCP controls at retail.

The purpose of this document is to initiate the rulemaking required to bring about these changes in the FSIS program. This document will also explain these changes in the context of a broad and long-term strategy to improve the safety of meat and poultry products. The safety of any food product can be affected—positively or negatively—at virtually every step in the process of producing the agricultural commodity on the farm, converting the agricultural commodity into a food product through slaughter and other processing, distributing the product to the consumer, and preparing the product for consumption. While this document focuses on changes that are needed within FSIS-inspected establishments, these changes are part of a broader food safety strategy. This strategy addresses each step in the process and takes a long-term approach to building a comprehensive food safety system that works effectively to protect consumers by preventing food safety problems.

To place the regulatory program in context, this document will first describe the origins and history of the FSIS program, the problem of foodborne illness in the United States, and FSIS's food safety objectives and proposed strategy for achieving them.

Origins and History of the FSIS Program

The following historical account briefly describes the purposes and operation of the inspection program from its late-nineteenth century inception through the current efforts to improve the program.

1890–1945

Federal meat inspection legislation dates from 1890, when countries in Europe raised questions about the safety of American beef. Congress gave the U.S. Department of Agriculture (USDA) responsibility for ensuring that exports would meet European requirements and, in 1891, for conducting ante- and postmortem inspection of livestock slaughtered for meat intended for distribution in the United States.

In 1906, the graphic picture of insanitary conditions in meat-packing establishments described in Upton Sinclair's novel *The Jungle* outraged the U.S. public. Congress responded by passing the Federal Meat Inspection Act (FMIA), one of the first Federal consumer protection measures. It established sanitary standards for slaughter and processing establishments, and mandated antemortem inspection of animals (cattle, hogs, sheep, and goats) and postmortem inspection of every carcass.

It also required the continuous presence of Government inspectors in all establishments that manufactured meat products for commerce. Because the program depended heavily on veterinary skills, it was implemented by USDA's Bureau of Animal Industry which, during that first year, oversaw the inspection of nearly 50 million animals.

The companion Food and Drug Act of 1906 was implemented by a different section of USDA, the Bureau of Chemistry. It covered the safety of all food products except meat and poultry, but it did not require continuous inspection. The Food and Drug Administration (FDA), which now implements the law, was formed in USDA in 1930 and transferred to the Public Health Service in 1940. Meat inspection, which primarily focused on carcass inspection by veterinarians, remained in USDA.

The meat inspection program that developed early in this century used organoleptic methods, based on sight, touch, and smell. The major public health concerns of the time were the potential for transmission of diseases from sick animals to humans and the lack of sanitary conditions for animal slaughter and production of processed products. The purpose of carcass inspection was to keep meat from diseased animals out of the food supply. Federal inspectors under the supervision of veterinarians checked every live animal and every carcass for signs of disease. They also watched for insanitary practices and the use of dangerous preservatives.

In addition to requiring carcass-by-carcass inspection in slaughter establishments, the 1906 meat inspection law provided for continuous USDA inspection of processing operations. Processing, which for the most part consisted of cutting and boning whole carcasses and the production of sausages, ham, and bacon, was usually done in or near the slaughterhouse. Processing was viewed as an extension of slaughter and was conducted by the same FSIS personnel. From the inception of the Program, however, the Agency recognized that, in processing inspection, the inspector focused on the operation of the overall production line, not on each production unit (in contrast to slaughter inspection, where inspectors focused on each carcass).

The FMIA covered all meat and meat products in interstate commerce. It did not cover poultry. At that time, chickens and turkeys were produced mainly on small farms for personal consumption or sale in the immediate area. They were inspected only by the purchaser.

1946–1975

Developments after World War II had a major impact on the meat and poultry industry. New establishments opened, beginning a surge of growth that continued through the 1950's and 1960's. The market for dressed, ready-to-cook poultry expanded rapidly, and both the meat and the poultry industries began turning out many new kinds of processed products. An increasing proportion of the total meat and poultry supply was being processed into hams, sausages, soups, frankfurters, frozen dinners, pizza, and so forth. Between 1946 and 1976, the volume of such products almost quadrupled.

New technology, new ingredients, and specialization added complexity to the once-simple processing industry. Small establishments, many producing solely for intrastate commerce, began producing new products outside the slaughterhouse environment. Processing inspection could no longer be managed as an extension of slaughter inspection.

The growth of the processing sector presented the inspection program with major challenges. First, the skills needed by the Agency called increasingly on the disciplines of food technology and microbiology, along with those of veterinary medicine. The Agency began to recruit and develop more people with the specialized skills necessary to design processing inspection systems.

Second, more inspectors were needed to meet the industry's growing production and geographic expansion. A system of ''patrol'' inspection assignments, with one inspector visiting several processing establishments daily, was devised to fulfill the statutory requirement for continuous inspection in those establishments.

Third, new technologies made it difficult for consumers to check levels of fat, water, and other ingredients used as fillers, increasing the risk of economic adulteration. As a result, USDA inspectors were increasingly called on to protect consumers in this technically complex area. Controlling the use of certain vegetable proteins as

ingredients in meat food products, for example, became important, because vegetable proteins can mask the addition of water to a product. The development of equipment to salvage formerly discarded high-protein tissue from bones and fatty tissue made time-temperature requirements necessary to guard against the growth of spoilage organisms. Standards had to be set for the use of these ingredients and the labeling of products containing them.

Meanwhile, better animal husbandry practices had improved animal health and reduced the public health risk from diseased carcasses. The Agency's extensive, statutorily mandated carcass-by-carcass inspection continued, however, with the important objective of eliminating from commerce the unpalatable signs of disease (such as tumors and lesions), meat from animals with diseases that could pose a human health risk (such as salmonellosis or cysticercosis), fecal contamination of meat and poultry carcasses, and visible damage (such as bruises). Establishment sanitation also remained an important object of inspection in both slaughter and processing facilities.

The Poultry Products Inspection Act (PPIA) of 1957 made inspection mandatory for all poultry products intended for distribution in interstate commerce. It was modeled after the Federal Meat Inspection Act.

The potential for unseen health hazards in the food supply also attracted increasing regulatory attention. In 1962, Rachel Carson's *Silent Spring* raised public awareness of the possible harmful effects of pesticides and other chemical contaminants in food. In 1967, the Agency established the National Residue Program, the Federal Government's principal regulatory mechanism for determining and controlling the presence and level of those chemicals in meat and poultry that may present a public health concern.

Because of the increasing volume and complexity of food production and the potential for various forms of adulteration that consumers could not, by themselves, determine, Congress enacted new legislation during this period to assure the safety and wholesomeness of all foods, including meat and poultry products. The 1958 Food Additives Amendment of the Federal Food, Drug, and Cosmetic Act (FFDCA) provided for FDA approval of new food additives and their conditions and levels of use.

The Wholesome Meat Act of 1967 and the Wholesome Poultry Products Act of 1968 amended the basic laws governing mandatory meat and poultry inspection to assure uniformity in the regulation of products shipped in interstate, intrastate, and foreign commerce. These Acts provide the statutory basis for the current meat and poultry inspection system. Both Acts gave USDA new regulatory authority over allied industries, including renderers, food brokers, animal food manufacturers, freezer storage concerns, transporters, retailers, and other entities. Both Acts incorporated adulteration and misbranding prohibitions tied to important provisions of the FFDCA relating to food and color additives, animal drugs, and pesticide chemicals. Both Acts provided stronger enforcement tools to USDA, including withdrawal or refusal of inspection services, detention, injunctions, and investigations. Both Acts extended Federal standards to intrastate operations, provided for State-Federal cooperative inspection programs, and required that State inspection systems be ''at least equal to'' the Federal system.

Also, under these Acts, meat and poultry products from foreign countries that are sold in the United States must have been inspected under systems that are equivalent to that of USDA.

1970s–Present: Increasing Demand for Inspection

By the 1970s, the need to focus on ''invisible'' hazards to public health had raised the ratio of analytical to organoleptic activities, and the ratio of out-of-plant to in-plant activities. The bulk of the Agency's resources continued to be allocated, however, to in-plant activities addressing the issues of animal disease and establishment sanitation. During the 1970s, national budget constraints reduced the funds available for inspection throughout the United States. As individual States exercised their right to request that the Agency take over their inspection programs, FSIS had either to eliminate some inspection activities or change the way they were performed, to provide the additional coverage.

The driving force behind FSIS's program changes from the 1970s on was the need to keep up with industry's expansion and its productivity gains, including the incorporation of automation in the slaughter process that increased the rate at which carcasses could move through the slaughter facility (typically referred to as ''line speed''). Automation has had a particularly great impact on poultry operations, where inspectors have had to face faster and faster line speeds, which today can be as high as 91 birds per minute.

The industry changed in many ways during this period. The poultry industry became, to a large extent, vertically integrated, with large companies controlling each step of the process from production of birds to slaughter, processing, distribution, and marketing of chicken and turkey products under brand names. The beef and pork industries grew, but generally did not become vertically integrated. Beef cattle and swine continued to be produced by a large number of independent farming businesses. Consolidation occurred in slaughter and processing operations, and production increased. Increased production meant more meat and poultry products awaited inspection by FSIS inspectors.

The Agency strained to keep pace with an industry radically different in scale and scope from what it had been in 1906. In September 1976, the Agency hired the management consulting firm of Booz, Allen and Hamilton, Inc., to perform an in-depth study to find less costly ways to inspect meat and poultry that would not reduce the level of consumer protection. The study recommended, among other things, that FSIS:

- Use quality control mechanisms to shift responsibilities from inspectors to the establishment, giving inspectors a verification responsibility.
- Establish microbiological criteria for finished products.
- Explore substitution of air chilling for water chilling of poultry carcasses.
- Require chlorination of chiller water for poultry.
- Expand food safety education for consumers and food handlers.

The study elicited a generally negative response from consumer groups and some members of FSIS's workforce, who interpreted the recommended role changes as an abdication of Agency responsibility. Anticipating higher costs and concomitant price hikes, industry also objected to the recommendations. FSIS decided to pursue only some of the recommendations.

One that it did pursue in processing establishments, the voluntary Total Quality Control (TQC) program, was implemented in 1980. The General Accounting Office (GAO) had recommended a TQC-type program in December 1977, to afford the Agency flexibility to tailor inspection frequency to individual establishments' needs. This program applied a different kind of inspection to establishments that FSIS approved for a self-monitored production control program designed to assure that processed products would meet regulatory requirements. In those

establishments, the inspector, instead of personally generating production process information, used establishment production records on the production process, supplemented by in-plant observations, to verify that product was in compliance. In many establishments, TQC reduced the time needed for inspection, but the statutory provision for ''continuous'' inspection meant that, even under TQC, an inspector had to visit the establishment at least daily.

In 1978, the Agency issued its own report, ''A Strengthened Meat and Poultry Inspection Program.'' Among other things, the report observed that the poultry postmortem system had been designed before both the vertical integration of the poultry industry and the increasing attention to production control, which had helped producers overcome major animal and poultry health problems. With the introduction of high-speed production lines, the traditional inspection system had become ''severely stressed,'' with inspectors ''forced to work at speeds well over those at which peak effectiveness is expected.'' Scientific evidence indicated that with the improvement in animal health, little of the carcass examination performed by inspectors was necessary to protect public health. However, carcass-by-carcass inspection continued to address the wholesomeness and quality aspects of meat and poultry that consumers demanded.

Between 1980 and 1986, the Agency introduced what became known as streamlined inspection systems (SIS) in high-speed poultry slaughter operations. These systems shifted routine tasks that controlled for quality, rather than safety, from inspectors to establishment employees. Since an increasing amount of the poultry (and meat) supply was being produced under brand names, the Agency believed that establishments would be motivated to protect the reputation of their products by performing systematic quality control for visible, unpalatable defects. Under streamlined inspection, establishment employees, working under FSIS supervision, would perform detection and trimming of carcass defects that affect the ''quality,'' but not the ''safety'' of the product—functions previously performed by FSIS inspectors. The attempt to streamline carcass inspection by shifting non-public health tasks to the industry was criticized by consumer groups and inspectors, who interpreted the modernization initiative as a pretext for deregulation.

In 1986, Congress granted the Agency the authority to vary the frequency and intensity of inspection in processing establishments on the basis of the risk presented by the particular establishment and process. Again, FSIS's proposal to implement this authority was interpreted by consumer groups as an effort to reduce inspection. They opposed it, as did some Agency employees. Industry members supported the concept but were skeptical about how it would be implemented. For lack of support, the Agency withdrew its proposal, and the legislative authority for it expired in 1992.

Each of the foregoing modernization initiatives aroused the same concerns: Increased line speeds compromised job performance; new procedures had not been adequately or objectively tested; and, generally, streamlined slaughter inspection policies would not protect consumers. While SIS for poultry survived, the controversy blocked FSIS's attempt to extend SIS to cattle. A special review in 1990 by the National Academy of Sciences (NAS) pointed out deficiencies in the current system's handling of microbiological hazards but concluded that a SIS for cattle would be at least as effective as traditional inspection. However, consumers and the Agency's inspection workforce equated SIS for cattle with deregulation—license for industry to increase line speeds at the expense of public health. Congress ordered the Agency to stop the pilot tests then in progress in five cattle operations.

Today, FSIS inspectors perform hundreds of tasks during slaughter and processing operations. Slaughter inspection occurs in two phases: ante- and postmortem. During antemortem inspection, the inspectors observe all red meat animals at rest and in motion, segregating any abnormal animals they detect before the animals enter the slaughter facility. Based on further examination by a Veterinary Medical Officer (VMO), abnormal animals are either condemned or allowed to enter the slaughter process under special handling.

Because the large number of chickens and turkeys FSIS inspects (more than 6 billion slaughtered annually) makes antemortem bird-by-bird inspection impracticable, inspectors or VMO's conduct the antemortem inspection of poultry on a flock or lot basis. The poultry are observed while in coops or grouped for slaughter, before or after they are removed from trucks. Abnormal birds are condemned.

Antemortem inspection can detect some diseases (for example, rabies, listeriosis, and heavy metal toxicosis) through distinct clinical signs that cannot be detected by gross postmortem inspection. Additionally, some types of microbial diseases that can seriously contaminate the slaughter environment, such as abscesses and anthrax, can be detected by antemortem inspection. In those cases, the affected animals are prevented from entering the slaughterhouse.

During the postmortem phase of Federal inspection, the viscera and carcasses of all animals and birds slaughtered are examined by an FSIS inspector on the processing line. (See Figures 1 and 2 for illustrative schematics of beef and broiler chicken slaughter.) Many of the bacteria implicated in cases of foodborne illness live in the intestinal tracts of meat animals and poultry, present no evidence of overt pathologies in the animal, and can be shed in the feces. For this reason, line inspectors require physical removal of visible fecal and ingesta contamination of flesh.

For red meat, inspectors examine the heads, viscera, and carcass at one or more postmortem inspection stations. For poultry the viscera, carcasses, and, for older poultry, heads are examined at a single postmortem inspection station. To detect abnormalities at these stations, the red meat inspector performs a sequence of observations, palpations, and incisions of tissues; the poultry inspector, a sequence of observations and palpations. For both red meat and poultry, visible contaminants (such as feces), damage, and other abnormalities are detected and eliminated to ensure only meat and poultry that appear fit for human consumption ''pass'' inspection. Only VMO's and VMO-supervised inspectors make the final determination.

BILLING CODE 3410–DM–P

Figure 1. Beef Slaughter

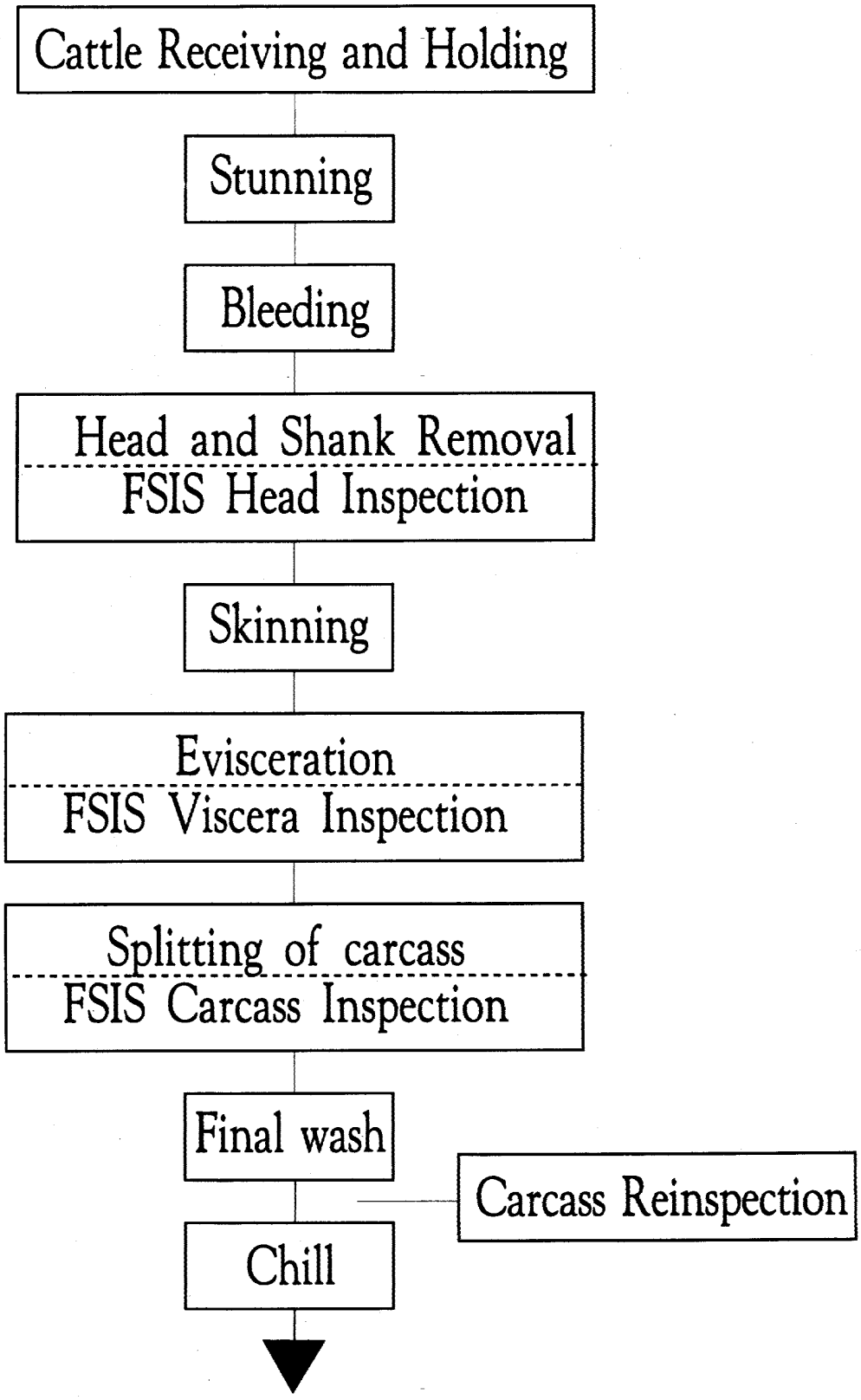
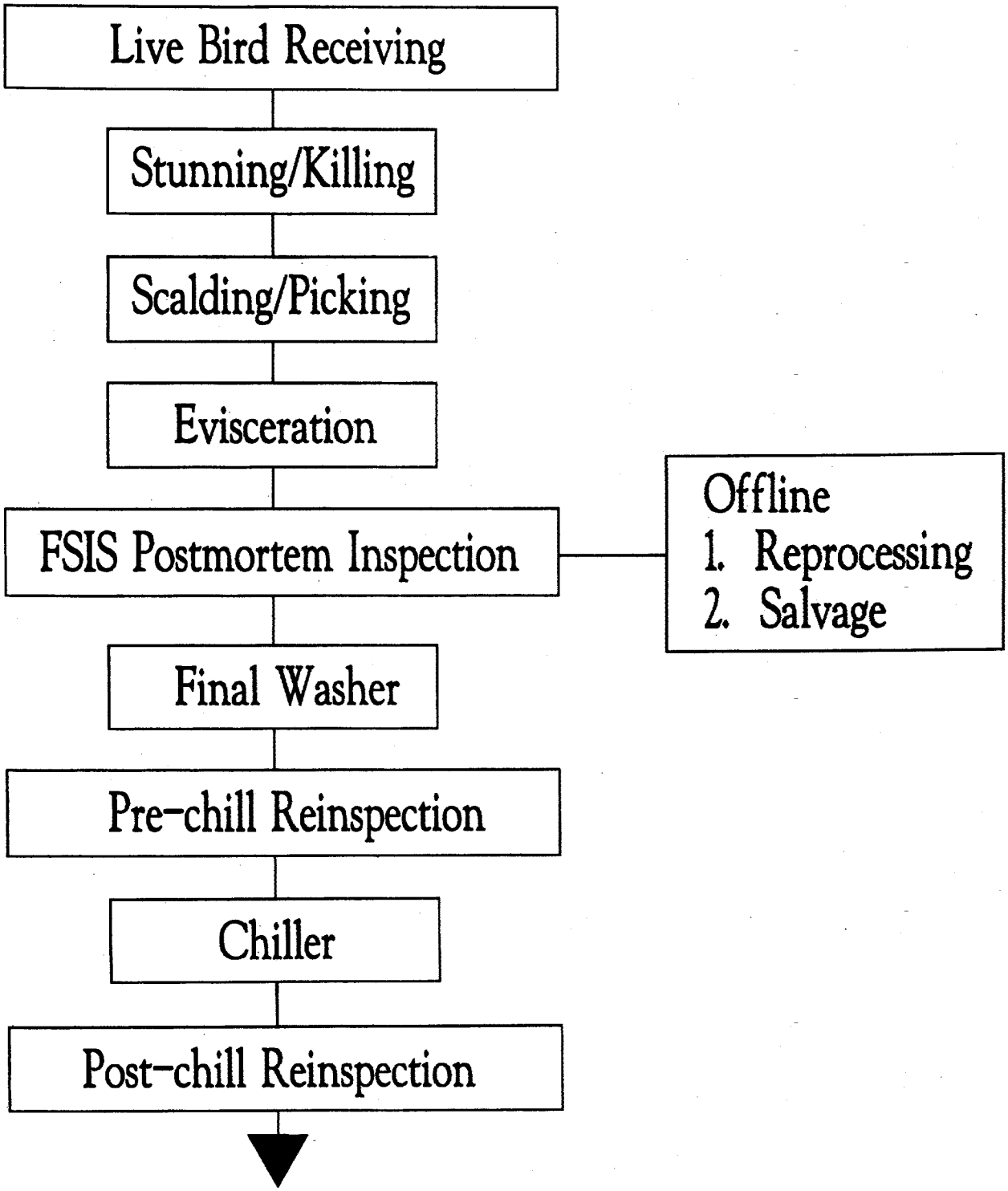


Figure 2. Broiler Chicken Slaughter



BILLING CODE 3410–DM–C

The prevention of ingesta and fecal contamination of beef and poultry carcasses in slaughter establishments is a focal point of the current inspection system, because contamination of the flesh with feces and ingesta is a potential cause of contamination of meat and poultry products with harmful bacterial pathogens, such as *Salmonella, Campylobacter* and *E. coli* 0157:H7. Contamination can occur as a result of feces entering the slaughter facility on the external surface of the animal and contaminating the carcass during the skinning or defeathering process or as a result of ingesta or feces being spilled from the intestinal tract during evisceration or other steps in the process. Meat and poultry carcasses found to bear fecal contamination must be condemned or, if possible, reworked to remove the contamination in an accepted manner. Removing visible fecal contamination is important, but it does not assure the absence of harmful bacteria that cannot be detected visually.

The law requires inspected meat and poultry products to bear an official inspection legend (21 U.S.C. 601(n)(12), 453(h)(12)). Specifically, the words ''inspected and passed'' must appear on meat products found not to be adulterated (21 U.S.C. 606, 607; 9 CFR 312.2, 312.3); ''inspected for wholesomeness by U.S. Department of Agriculture'' must appear on poultry products (9 CFR 381.96). The term ''wholesome'' has traditionally been applied to meat or poultry found upon visual inspection to be free of disease, not decomposed, and to be otherwise fit for human consumption. While ''wholesome'' as used in this context is not intended to be synonymous with ''safe,'' consumers could reasonably infer a connection between ''wholesomeness'' and food safety. Similarly the words ''inspected and passed'' on meat products could be understood by consumers as a statement about safety, despite the fact that organoleptic inspection does not address invisible hazards, such as pathogenic microorganisms.

This problem concerning the meaning of the inspection legend arises in part from the fact that the requirement to place an inspection legend on every product that passes inspection was adopted before the safety concerns posed by pathogenic microorganisms, drug residues, and other invisible hazards came to the fore. Visual inspection does not directly address these safety issues on a carcass-by-carcass or product-by-product basis. Thus, some contend that the inspection legends serve only to mislead contemporary consumers and should be discontinued. FSIS invites public comment on this issue.

Of the 129,831,110 meat-animal carcasses inspected during Fiscal Year 1993, 384,543 (or .3 percent) were condemned for disease, contamination, or adulteration during ante- or postmortem inspection. Of the 7,085,491,852 poultry carcasses inspected that year, 63,926,693 (or .9 percent) were condemned. Today, more than 7,300 FSIS inspectors enforce the inspection laws in approximately 6,200 meat and poultry establishments. Inspection activities start prior to slaughter and continue throughout processing, handling, and packaging.

FSIS ensures compliance with inspection laws and regulations outside inspected establishments through control and condemnation of misbranded or adulterated products. Specifically, during FY 1993, FSIS detained suspect products 796 times (involving 13,081,409 pounds of product) and monitored product recalls 36 times (involving 5,726,378 pounds of product). During the same period, 145,526 meat and poultry product labels were reviewed; 10,154 were not approved. Other measures FSIS uses to enforce the regulations include withholding inspection pending correction of serious problems, controlling product distribution, working with companies to recall violative products, and seeking court-ordered product seizures when necessary.

The Performance-Based Inspection System (PBIS) is a modernization initiative implemented in processing establishments during 1989. PBIS is a structured, automated information system that helps the Agency document findings resulting from inspector tasks; record deficiencies found and actions taken; and discuss deficient findings and corrective actions with establishment management. PBIS is intended to make processing inspection more uniform nationwide and provides FSIS with its first easily accessible database on establishment performance. It enables the Agency to capture, store, and sort the vast quantities of information generated by the 13 million inspection tasks performed in processing establishments each year. These data allow the Agency to examine the long-term operation of a particular establishment or the performance of a particular control point nationwide. Decisions on inspection intensity are based on these data, although the frequency is never less than one visit per day.

FSIS expects to implement PBIS in slaughter operations during FY 1996.

Foodborne Illness in the United States

The safety of the meat and poultry supply has been widely discussed during the past few years. Although food safety can be affected by multiple factors, including animal drug and pesticide residues and unintentional environmental contaminants, the following discussion focuses on pathogenic microorganisms that are associated with foodborne illness, including the illness and preventable deaths associated with meat and poultry consumption. Pathogenic microorganisms are widely recognized by scientists to be the most significant causes of foodborne illness.

Foodborne illness can strike individuals of all ages, sexes, nationalities, and socioeconomic levels. The most common types of foodborne illness associated with pathogenic microorganisms typically appear as acute gastroenteritis with sudden onset of vomiting or diarrhea, or both, with accompanying abdominal pain. However, the exact combination of symptoms may vary widely, depending on the type of microorganism and the immune status of the person infected. For example, certain types of bacteria often cause bloody diarrhea, including *E. coli* 0157:H7 and, in a smaller percentage of cases, *Campylobacter jejuni. E. coli* 0157:H7 produces a strong toxin (''shiga-like'' toxin) which can lead to blood clotting abnormalities and kidney failure (hemolytic uremic syndrome) and can cause death, especially in young children and the elderly. Even if recovery from the acute illness is complete, 15–30 percent of persons with hemolytic uremic syndrome will have evidence of chronic kidney disease. While *Salmonella* ordinarily causes transitory and non-life-threatening acute gastroenteritis, *Salmonella* can get into the bloodstream of some infected patients, particularly patients who are very young, very old, or immunosuppressed (such as persons with AIDS); these bloodstream infections can have serious complications, including death. Infections caused by *Salmonella* may also trigger autoimmune phenomena, such as reactive arthritis, which may result in long-term disability.

While there is general consensus that foodborne illness is a major cause of morbidity and mortality in this country, estimates of the incidence of foodborne illness vary widely. The Centers for Disease Control and Prevention (CDC) maintains a national foodborne disease surveillance system, but the data in this

system are recognized not to provide an accurate estimate of foodborne disease incidence. With the exception of a few pathogens, the data deal only with outbreaks (two or more cases of illness linked to a common source); are based on voluntary reporting by State health departments; and are dependent almost entirely on passive surveillance (that is, cases and outbreaks voluntarily reported to local health authorities).

A somewhat better picture of disease incidence can be obtained through national laboratory-based reporting systems. The model for this is the CDC system for reporting of salmonellosis. Again, however, data are in most instances passively collected, and are dependent on physicians submitting cultures; if a patient does not see a doctor, or the doctor does not collect a stool culture, the case does not enter the reporting system. Further, of the major foodborne pathogens, laboratory-based surveillance is available only for *Salmonella*. Recognizing these deficiencies, a number of groups have attempted to estimate actual rates of disease occurrence, drawing both from CDC databases (with their inherent limitations, discussed above) and extrapolating from population-based studies in specific geographic areas. ''Best estimates'' of the incidence of specific diseases, and the percentage of these diseases thought to be foodborne, are provided in Table 1, below (together with the source of these estimates). These estimates are in basic agreement with compilations put together by expert committees of the National Academy of Sciences and, most recently, by the Council for Agricultural Science and Technology.

Taken together, these data suggest that foodborne pathogens account for up to 7 million cases of foodborne illness each year, and up to 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated annually with meat and poultry products contaminated with pathogenic microorganisms. Even these estimates may be low; at least one investigator has suggested that total cases of foodborne illness may reach 33 million cases a year, with up to 9,000 deaths.

TABLE 1.—SOURCES OF DATA FOR SELECTED FOODBORNE PATHOGENS, 1993

Pathogen	Total cases (#)	Total deaths (#)	Source(s) for case and death estimates	Percent foodborne (%)	Source
Bacteria:					
Campylobacter jejuni or coli	2,500,000	200–730	Tauxe	55–70	Tauxe et al.
Clostridium perfringens	10,000	100	Bennett et al	100	Bennett et al.
Escherichia coli O157:H7	10,000–20,000	200–500	AGA Conference	80	AGA Conf./CDC comm.
Listeria monocytogenes	1,795–1,860	445–510	Roberts and Pinner	85–95	Schuchat.
Salmonella	800,000–4,000,000	800–4,000	Helmick et al./Bennett et al	87–96	Bennett et al./Tauxe & Blake.
Staphylococcus aureus	8,900,000	7,120	Bennett et al	17	Bennett et al.
Parasite:					
Toxoplasma gondii	4,111	82	Roberts et al	50	Roberts et al.

Sources:

American Gastroenterological Association Consensus Conference on *E. coli* O157:H7, Washington, DC, July 11–13, 1994.

Bennett, J.V., S.D. Holmberg, M.F. Rogers, and S.L. Solomon. 1987. ''Infectious and Parasitic Diseases,'' In R.W. Amler and H.B. Dull (Eds.) *Closing the Gap: The Burden of Unnecessary Illness.* Oxford University Press, New York.

Helmick, C.G., P.M. Griffin, D.G. Addiss, R.V. Tauxe, and D.D. Juranek. 1994. ''Infectious Diarrheas.'' In: Everheart, JE, ed. *Digestive Diseases in the United States: Epidemiology and Impact.* USDHHS, NIH, NIDDKD, NIH Pub. No. 94–1447, pp. 85–123, Wash, DC: USGPO.

Roberts, T., K.D. Murrell, and S. Marks. 1944. ''Economic Losses Caused by Foodborne Parasitic Diseases,'' *Parasitology Today.* vol. 10, no. 11: 419–423.

Schuchat, Anne, CDC, personal communication with T. Roberts at the FDA Science Forum on Regulatory Sciences, Washington, DC, September 29, 1994.

Tauxe, R.V., ''Epidemiology of *Campylobacter jejuni* infections in the United States and other Industrialized Nations.'' In Nachamkin, Blaser, Tompkins, ed. *Campylobacter jejuni: Current Status and Future Trends,* 1994, chapter 2, pages 9–19.

Tauxe, R.V. and P.A. Blake, ''Salmonellosis'' rest of reference unknown.

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TABLE 2.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED HUMAN PATHOGENS, 1993

Pathogen	Foodborne illness		Foodborne* costs (bil $)	Percent from meat/poultry (%)	Meat/poultry related		Total costs* meat/poultry (bil $)
	Cases (#)	Deaths (#)			Cases (#)	Deaths (#)	
Bacteria:							
Campylobacter jejuni or coli	1,375,000–1,750,000	110–511	0.6–1.0	75	1,031,250–1,312,500	83–383	0.5–0.8
Clostridium perfringens**	10,000	100	0.1	50	5,000	50	0.1
Escherichia coli 0157:H7	8,000–16,000	160–400	0.2–0.6	75	6,000–12,000	120–300	0.2–0.5
Listeria monocytogenes	1,526–1,767	378–485	0.2–0.3	50	763–884	189–243	0.1–0.2
Salmonella	696,000–3,840,000	696–3,840	0.6–3.5	50–75	348,000–2,880,000	348–2,610	0.3–2.6
Staphylococcus aureus**	*1,513,000*	1,210	1.2	50	*756,500*	605	0.6
Subtotal	3,603,526–7,130,767	2,654–6,546	2.9–6.7	N/A	2,147,513–4,966,884	1,395–4,191	1.8–4.8

TABLE 2.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED HUMAN PATHOGENS, 1993—Continued

Pathogen	Foodborne illness		Foodborne* costs (bil $)	Percent from meat/poultry (%)	Meat/poultry related		Total costs* meat/poultry (bil $)
	Cases (#)	Deaths (#)			Cases (#)	Deaths (#)	
Parasite:							
Toxoplasma gondii	3,056	41	2.7	100	2,056	41	2.7
Total	3,606,582–7,133,823	2,695–6,587	5.6–9.4	N/A	2,149,569–4,968,940	1,436–4,232	4.5–7.5

The costs of the foodborne illnesses (see Table 2, above) are borne by those who become ill and their families, coworkers, and employers, as well as the food industries, and taxpayers. Costs to stricken individuals include medical bills, time lost from work, pain and inconvenience. Food industry costs include possible product recalls, establishment closings and cleanup, and higher premiums for product liability insurance. Perhaps most costly in the long term is loss of product reputation and reduced demand when an outbreak is traced back and publicized. These and other ''defensive'' industry costs of foodborne disease run in the millions of dollars annually and are, for the most part, entirely avoidable. Taxpayer costs include medical treatment for those who cannot afford it and higher health insurance premiums.

Other taxpayer costs include public health-sector expenses to operate a disease surveillance system and to investigate and eliminate disease outbreaks. Approximately $300 million is spent on microbial foodborne disease annually by the Federal public health-sector. Federal costs average about $200,000 per foodborne illness outbreak.

The Department's Economic Research Service and CDC estimate the cost of all foodborne illness in 1993 to have been between $5.6 and $9.4 billion. Meat and poultry products were associated with approximately $4.5–$7.5 billion; the remaining $1.1 to $1.9 billion was associated with non-meat and poultry sources. Table 2 summarizes data on a pathogen-by-pathogen basis.

Foods contaminated with pathogenic microorganisms can lead to infection and illness in two major ways. The first is by direct consumption of the contaminated food under conditions that allow the survival of the pathogen or its toxin, such as when a meat or poultry product is consumed raw or undercooked, or products precooked during processing are recontaminated and consumed directly. The second is through cross-contamination in the kitchen or other food-handling areas, for example, when raw chicken or beef with a *Salmonella*-contaminated exterior contaminates a person's hands, a cutting board, countertop, or kitchen utensil, which then comes into contact with cooked product or foods consumed raw, such as salad. For some pathogens, such as *Salmonella,* it is likely that more cases of illness result from cross-contamination than from direct consumption of undercooked product.

Microbiological surveys of meat and poultry products have been conducted by FSIS over several decades. In cooked, ready-to-eat products, the frequency of pathogenic microorganisms has been relatively low. In regulatory testing programs of domestically produced, cooked, ready-to-eat meat and poultry products, for example, *Salmonella* has generally been found to be present in only about 0.1 percent of the samples tested and *Listeria monocytogenes* in about 1.5–3 percent of samples tested.

The frequency of pathogenic microorganisms in raw, ready-to-cook products has been greater. For example, FSIS has conducted surveys on the prevalence of *Salmonella* in various raw products, including broiler chickens, beginning as early as 1967. In these surveys, *Salmonellae* were isolated from 28.6 percent of 597 samples in 1967; from 36.9 percent of 601 samples in 1979; from 35.2 percent of 1693 samples in the 1982–1984 study; and from approximately 25 percent of the samples in the 1990–1992 study. FSIS studies on fresh pork sausage involved retail-size samples. *Salmonellae* were isolated from 28.6 percent of 566 samples in 1969, and from 12.4 percent of 603 samples in 1979. A benchmark study on raw beef was initiated in January 1987 and completed in March 1990. The prevalence of *Salmonella* in 25 gram portions was found to be 1.6 percent, the prevalence of *Listeria monocytogenes* was 7.1 percent and the prevalence of *E. coli* 0157:H7 was 0.1 percent.

In 1992, FSIS began a series of Nationwide Microbiological Baseline Data Collection Programs designed to provide a microbiological profile of various classes of inspected product. The first, on steer and heifer carcasses, was reported in January 1994. *Clostridium perfringens* was recovered from 2.6 percent of 2,079 carcasses; *Staphylococcus aureus* from 4.2 percent of 2,089 carcasses, *Campylobacter jejuni/coli* from 4.0 percent of 2,064 carcasses; *E. coli* 0157:H7 from 0.2 percent of 2,081 carcasses; and *Salmonella* from 1.0 percent of 2,089 carcasses.

The ongoing outbreaks of salmonellosis, attributed to consumption of contaminated meat, poultry and other food products, and the recent outbreaks of illness caused by *E. coli* 0157:H7 in undercooked ground beef, illustrate how serious the public health threat can be, even when the incidence of contamination of carcasses is relatively low.

For example, on January 13, 1993, a physician in Washington State reported to the Washington State Department of Health a cluster of children with Hemolytic Uremic Syndrome, a serious condition that is the major cause of acute kidney failure in children. Also reported was an increase in emergency room visits for bloody diarrhea. This outbreak was reported to CDC.

Cultures taken from symptomatic patients indicated that *E. coli* 0157:H7 was the causative organism. During January 16–17 an epidemiological case-control study conducted by Washington State and CDC strongly suggested the consumption of hamburgers at a chain of fast food restaurants as the source of the infection. The investigation revealed that the hamburger patties were cooked by the restaurants to a temperature below the Washington State standard of 155°F, and in some instances below the 140°F then recommended by FDA.

By February 4, 350 people in Washington State had contracted illnesses of the kind associated with *E.*

coli 157:H7 and, of these cases, 230 were culture-confirmed. In addition, 12 people had become ill in Idaho and 30 in Nevada. It was also learned that illness had occurred among 34 persons in San Diego, California, in December and January. The outbreaks in each of these States all had in common the consumption of hamburger at the same chain of fast food restaurants. The greater proportion of these cases were primary infections, that is, the persons affected became ill directly from eating contaminated hamburgers. The other cases were secondary infections—the affected persons contracted their illnesses through contact with a person who was infected with the pathogen.

Eventually, four people died and more than 500 other persons became ill during the course of the epidemic.

An important aspect of the Department's review of this experience was the finding that the winter 1992–93 outbreak was not caused by a failure in the operation of the inspection system as currently designed. Rather, it stemmed in part from an inspection system that does not directly require the reduction, minimization, or elimination, if possible, of pathogenic microorganisms in raw product leaving inspected establishments. The specific pathogen in this example was highly virulent, meaning that a very low dose was sufficient to cause illness. During the beef-grinding process, harmful bacteria can easily be spread throughout a large volume of product. When such product becomes widely distributed and is cooked inadequately to kill any pathogens that might be present, preventable deaths may result.

The Relationship Between Foodborne Illness and Consumer Knowledge and Behavior

The National Academy of Sciences' *Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS–C)* (1990) reiterated the theme of numerous other studies, ''* * * the public expects the government to ensure zero risk of meat-borne disease through inspection. The [NAS] committee heard little evidence that the public is aware that some bacterial contamination of raw meat is inevitable and no mention of the crucial role of food handling, preparation, and serving methods in limiting foodborne diseases.'' The disturbing but real fact that consumers fail to make a connection between their food handling behavior and safe food recurs throughout the literature on the subject.

Behavioral research shows that food habits are the most difficult of all forms of human behavior to change. This finding is supported by research of consumer knowledge and practices, which indicates that a large portion of the U.S. population lacks basic food safety information and skills and engages in food handling and preparation practices that epidemiological studies have linked with a significant number of foodborne illness outbreaks. Moreover, little correlation exists between consumers' food safety knowledge and their food handling and preparation practices. Even people who characterize themselves as ''knowledgeable'' do not necessarily follow good food safety procedures.

These findings about consumer behavior related to safe food handling and preparation support the need for a comprehensive pathogen reduction effort. Food safety can best be assured only if each participant in the food system—from the producer all the way through to the consumer—understands, accepts, and acts on his or her responsibility for food safety. While FSIS will pursue and support all possible means of consumer education and outreach, the Agency realizes that consumer education alone will not control pathogen-related foodborne illness. This is truer today than ever before, as more people in our society are assuming responsibility for food handling and preparation in the home and elsewhere, without experience in food preparation and knowledge of safe food handling and storage methods. These people include:

- Food service workers, many of whom are high-turnover, part-time, or teenaged workers who receive inadequate training;
- Men and women in the workplace, who have minimal time for food preparation and often little experience or interest in food preparation;
- Children, who are increasingly expected to shop for and prepare their own meals;
- Immigrants, who might not be able to read food handling instructions, or whose cultural practices include eating raw or rare meat and poultry products.

Vulnerable sectors of the population, more severely affected by foodborne illness, are also increasing in size:

- Immunocompromised persons (i.e., persons with diabetes, cancer, chronic intestinal diseases, organ transplants, and AIDS);
- Persons 65 years and older—a growing proportion of the population—who, due to the normal decline in immune response, are at increased risk.

In 1993, to increase awareness about pathogens, FSIS promulgated a regulation requiring safe handling labels on most raw meat and poultry products. The Agency's Meat and Poultry Hotline provides consumers with immediate responses to questions about meat and poultry handling and safety. These steps and other education activities are important but they are not a substitute for building into the meat and poultry production and regulatory system measures to reduce to the maximum extent possible the presence of pathogenic microorganisms in meat and poultry products purchased by U.S. consumers.

External Studies and Recommendations for Change

During the past decade, the National Academy of Sciences (NAS), the General Accounting Office (GAO), the National Advisory Committee on Microbiological Criteria for Food (NACMCF), and consumer groups have evaluated and called for change in the current inspection system.

In 1983, FSIS asked NAS to evaluate the scientific basis of its inspection system and recommend a modernization agenda. The resulting report, *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program*, was issued in 1985. This was the first comprehensive evaluation of the scientific basis for the Federal meat and poultry inspection system. The report provided a blueprint for change, recommending that FSIS focus on pathogenic organisms and require that all official establishments operate under a Hazard Analysis and Critical Control Point (HACCP) system to control pathogens and other safety hazards. This report ''encourages FSIS to move as vigorously as possible in the application of the HACCP concept to each and every step in establishment operations, in all types of enterprises involved in the production, processing, and storage of meat and poultry products.''

Two later NAS studies reinforced these recommendations, urging the Agency to focus on public health goals:

- *Poultry Inspection: The Basis for a Risk Assessment Approach* (1987) concluded that a risk-assessment approach is needed to evaluate health hazards associated with poultry. Critical control points at which known pathogenic microorganisms may be introduced into the poultry production system should be identified and monitored, preferably as part of a HACCP program.
- The most recent NAS report, *Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS–C)* (1990) stated that traditional meat inspection, relying on

organoleptic examinations, is not fully effective in protecting the public from foodborne health hazards. FSIS was urged to move to a risk-based inspection system targeted at significant public health risks, especially those associated with pathogenic microorganisms.

The GAO has also been advocating improvements in the present inspection system in reports and Congressional testimony. In numerous reports (see list below), GAO endorses HACCP as a scientific, risk-based system to better protect the public from foodborne illness. This sentiment is most clearly expressed in the 1994 *Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry,* which states:

> A HACCP system is generally considered the best approach currently available to ensure safe foods because it focuses on preventing contamination rather than detecting contamination once it has occurred.* * * To better protect the public from foodborne illnesses, we believe FSIS must now move to a scientific, risk-based inspection system. Such a system would allow FSIS to target its resources towards the higher risk meat and poultry products and establishments by increasing inspection of such products and establishments, developing methods or tools that would help inspectors detect microbial contamination, increasing product testing, and helping establishments develop and operate microbial testing programs.

This report further recommends that Congress ''revise the meat and poultry acts to provide FSIS with the flexibility and discretion to target its inspection resources to the most serious food safety risks.''

These basic recommendations are echoed in the five GAO reports describing the current inspection system and recommending changes to improve its effectiveness, listed below:

''Meat Safety: Inspection System's Ability to Detect Harmful Bacteria Remains Limited'' (1994);

''Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety'' (1993);

''Food Safety: Building a Scientific Risk-Based Meat and Poultry Inspection System'' (1993);

''Food Safety: Inspection of Domestic and Imported Meat Should be Risk-Based'' (1993);

''Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply'' (1992).

A third major proponent of HACCP is the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which was established in 1988 by the Secretary of Agriculture to advise and provide recommendations to the Secretaries of Agriculture and of Health and Human Services on developing microbiological criteria to assess food safety and wholesomeness. Since 1989, NACMCF has prepared a series of reports on the development and implementation of HACCP. As one of its first tasks, the Committee developed ''HACCP Principles for Food Production'' in November 1989. In this report the Committee endorsed the HACCP system as a rational approach to ensure food safety and delineated seven HACCP principles to standardize HACCP in the Committee's own work, as well as in industry, regulatory applications, and training. In 1992, the Committee issued an updated guide, ''Hazard Analysis and Critical Control Point System.''

To describe the HACCP system more concretely, in 1993 NACMCF published *The Role of Regulatory Agencies and Industry in HACCP.* In that report, NACMCF articulated the roles of regulatory agencies and industry in implementing HACCP, and recommended what the responsibilities of FDA, USDA, other agencies and industry should be during various phases of HACCP implementation.

In June 1993, NACMCF developed a model, ''Generic HACCP for Raw Beef,'' which provides a HACCP plan for beef slaughter and processing (see Appendix). It focuses on the slaughter and processing portions of the total ''farm to consumption'' scope of a complete HACCP program.

Similar recommendations for program change have come from consumer, industry, State, and local government representatives, as well as other constituent groups. Consumer representatives at recent public hearings and the HACCP Round Table held in March 1994 supported implementation of HACCP throughout the meat and poultry industry.

Industry groups, in clarifying their support for HACCP to control pathogens, contend that HACCP-based food production, distribution, and preparation by industry can do more to protect public health than any Federal inspection program. They recommended that HACCP be used to anticipate microbiological hazards in food systems and to identify risks in new and traditional products. State departments of health and agriculture also endorsed the HACCP approach.

FSIS Agenda for Change

The meat and poultry inspection program currently addresses many matters of great importance to the safety and quality of the food supply, including supervision of industry compliance with sanitation standards, exclusion of diseased animals from the food supply, examination of carcasses for other visible defects that can affect safety and quality, inspecting for economic adulteration, and monitoring for chemical residues. These activities respond to some of the public's most basic expectations regarding the safety and quality of the food supply and reflect the standards and requirements established by Congress in the laws FSIS administers. FSIS is strongly committed to effectively implementing these statutory requirements.

As the experience of recent years and the many external studies and reports indicate, however, there is a need for fundamental change in the FSIS program. The most critical reason for change is the need to ensure that the FSIS inspection program is fully meeting its paramount obligation to protect public health. To meet this obligation, there is a pressing need to better address the public health problem of foodborne illness associated with the consumption of meat and poultry products.

As documented in the preceding sections, many cases of foodborne illness are caused annually by pathogenic microorganisms that enter the food supply during the slaughter and processing of meat and poultry products. With respect to raw meat and poultry products, the current system of inspection addresses this problem only indirectly, by enforcing sanitation requirements and inspecting for visible fecal and ingesta contamination and other visible defects that can be pathways for contamination of carcasses by pathogenic microorganisms.

The current system must be enhanced to deal more directly with pathogenic microorganisms. In particular, the system needs to be changed to make better use of the science and tools of microbiology to reduce, and where possible eliminate, pathogenic microorganisms. Such change is needed to protect public health.

Change is also needed to clarify the respective responsibilities of the meat and poultry industries and the FSIS inspection program when it comes to the safety of the food supply. Companies producing meat and poultry products are responsible for ensuring that their products are safe and do not violate any of the statutory provisions defining adulteration and misbranding. FSIS is responsible for inspecting products and facilities to verify that these requirements have been met and for taking appropriate remedial and enforcement actions when the requirements have not been met.

This line between industry and FSIS responsibility has become blurred. This may be due in part to the continuous presence of FSIS inspectors in meat and poultry establishments and the statutorily mandated USDA inspection legend, which together may have encouraged some establishments to rely on FSIS to ensure the safety of the establishment's products rather than take full responsibility themselves for the safety of their products. Because the FSIS inspector is obligated to prevent adulterated product from leaving the establishment, some establishments may operate on the assumption that what is not specifically prohibited or detected by the FSIS inspector may continue. This is not acceptable.

Likewise, the FSIS inspection program has too often taken on the burden of expending significant inspectional resources to bring establishments into compliance—such as in cases of repeat violators of sanitation standards—rather than finding efficient means to hold establishments accountable for complying with applicable standards. As a result, the inspection resources needed to ensure that all establishments have appropriate production controls are frequently spent on intensified inspection of poor performers. For these reasons, the lines of responsibility for food safety must be clarified.

Finally, change is needed to move toward a more preventive approach to ensuring the safety of food. The current system relies too heavily on FSIS inspectors to detect and correct problems after they have occurred, whether in establishments or after the product has left the establishment. This is not the most efficient use of FSIS resources, and, especially in the case of pathogenic microorganisms, it is not effective in protecting public health. Many meat and poultry establishments, as well as other segments of the food industry, have found that safety can best be ensured by systems designed to prevent food safety problems. To protect public health and make the best use of its resources, FSIS needs to build the principle of prevention into its inspection system.

The changes FSIS plans in its inspection program—targeting pathogenic microorganisms, setting priorities on the basis of public health risk, clarifying roles and responsibilities, and building in the principle of prevention—constitute an institutional paradigm shift that can significantly enhance the effectiveness of the FSIS program and reduce the risk of foodborne illness.

To achieve such change, FSIS must articulate its food safety goal in broad terms and adopt a food safety strategy that will work to achieve both a real reduction of pathogens in the near term and, in the long term, the fundamental changes in the inspection program that are needed to better protect public health.

FSIS Food Safety Goal

It is tempting to think of food safety as an absolute. In an ideal world, there would be no cases of foodborne illness. The world we live in is, however, far from ideal. The production of the food that feeds 250 million Americans every day is an enormously complex task. It is undertaken in a natural environment where hazards, including pathogenic microorganisms, are common. It requires a level of technological intervention—in the form of machinery, chemicals, and processing—that itself can introduce hazards. And it is an enterprise that depends, in the end, on a vast array of human interventions and activities, which means that human error is a constant factor that can contribute to food safety hazards.

FSIS believes the public can understand that safety is not an absolute, and the laws FSIS administers do not speak in absolute terms. FSIS also believes, however, that public expectations are justifiably high when it comes to measures the food production system should take to reduce risk and ensure the safety of food. Furthermore, the laws FSIS administers set high standards—for example, meat and poultry products are deemed ''adulterated'' and thus unlawful if they are for any reason ''unhealthful''—and they empower FSIS to take actions needed to meet those standards and meet the public's high expectations concerning the safety of the food supply.

FSIS believes its food safety goal should be to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the food production process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood it will occur.

There is no single technological or procedural solution to the problem of foodborne illness, and the Agency's food safety goal will not be achieved overnight. Indeed, inherent in the nature of the Agency's goal is the concept that food safety requires continuous efforts to improve how hazards are identified and prevented. It is based on the public health principle that, on a continuing basis, society should seek out and take preventive measures to reduce the risk of illness. It reflects the Agency's belief that steps that can be taken today to reduce the risk of foodborne illness should be taken today, but that steps judged adequate today may not be judged adequate tomorrow.

In the case of the major enteric pathogens that contaminate meat and poultry products during the slaughter process, FSIS believes that the risk of foodborne illness associated with these pathogens is largely avoidable and can be minimized by proper implementation of HACCP. This does not necessarily mean absolute elimination of such pathogens, but it does mean preventing and reducing contamination with these pathogenic microorganisms to a degree that very substantially reduces and minimizes the risk of foodborne illness.

Achieving this food safety goal requires long-term commitment and action by Government and industry. It also requires general agreement on a regulatory strategy that can achieve the goal.

FSIS Food Safety Regulatory Strategy

FSIS believes that to achieve its food safety goal, and bring about the change described above, a new regulatory strategy is needed. The major elements of the Agency's proposed strategy are outlined in this section, with a brief explanation of how the regulatory changes FSIS is proposing in this document will advance the strategy.

1. *FSIS must clearly define the minimum requirements all establishments must meet to produce safe meat and poultry products and make establishments readily accountable for meeting them.* Good sanitation and basic good manufacturing practices (GMP's) are generally regarded as essential prerequisites for the production of safe food. The current FSIS program includes sanitation regulations that set out certain standards of cleanliness establishments are required to meet; and the Agency has provided guidance, in the form of a Sanitation Handbook, on how sanitation requirements can be met. FSIS also has promulgated regulations that impose various specific requirements, especially regarding processing operations, that might be characterized as GMPs.

In the sanitation area, however, FSIS has not spelled out clearly the responsibility every establishment has to install procedures that ensure sanitation requirements are met every

day, both before operations commence and during operation. In the GMP area, certain important food safety-related practices that have emerged in recent years have become recognized by the majority of the industry as appropriate GMPs, but they have not been made part of the basic regulatory requirement all establishments must meet.

FSIS believes it is important, especially for the near term, to codify certain minimum practices all establishments must observe to produce safe meat and poultry products and to improve the Agency's ability to hold establishments accountable for following those practices. Thus, FSIS is proposing: (1) to require that all establishments develop and adopt standard operating procedures for their sanitation programs, (2) to require that all slaughter establishments incorporate at least one effective antimicrobial treatment to reduce the levels of microorganisms on carcasses before they enter the chilling step, and (3) to codify specific time and temperature requirements for cooling of carcasses post-slaughter.

The majority of meat and poultry establishments already observe some or all of the practices FSIS is proposing to require. They are basic to producing a safe product, and FSIS believes all establishments should observe them. By codifying these practices in the Agency's regulations, FSIS will have an effective means to hold all establishments accountable for meeting them. Codifying these basic requirements is by no means a complete or long-term solution to the food safety problem but rather is part of the Agency's effort to ensure, as more fundamental improvements are being developed, that readily available improvements are incorporated into the system in the near term. FSIS invites comment on whether elements of current GMP's should be mandated by the Agency.

2. *FSIS must stimulate improvement in food safety practices by setting public health-oriented targets, guidelines, or standards all establishments must meet.* This is the centerpiece of the FSIS food safety strategy and the most important departure from the Agency's current regulatory approach. In its past regulation of the slaughter process and of raw, ready-to-cook meat and poultry products, FSIS has not clearly defined what safety means or set public health targets, guidelines, or standards for reducing the incidence of contamination of these products with human pathogens (pathogens that cause illness in humans). Consequently, there has been no basis for evaluating from an objective, public health standpoint whether the measures establishments have taken to prevent harmful contamination are adequate or should be deemed acceptable. FSIS has instead focused on managing its current system of visual inspection and encouraging industry efforts to reduce pathogens, but without an effective tool for requiring or evaluating those efforts.

FSIS believes that setting public health targets, guidelines, or standards is the most powerful and effective tool available for bringing about changes in FSIS-inspected establishments, especially slaughter establishments, that will reduce levels of pathogenic microorganisms and improve the safety of meat and poultry products. The concept is simply that, by establishing targets, guidelines, or standards establishments are required to meet, FSIS can stimulate the innovation and change needed to reduce risk from all sources of foodborne hazards—whether biological, chemical, or physical—and, at the same time, have a tool for holding all establishments accountable for achieving an acceptable level of food safety performance.

FSIS realizes that this new approach raises some new and difficult scientific and policy issues and thus may be controversial in some quarters. The most important issues concern the basis upon which the targets, guidelines, or standards (hereafter referred to generally as ''microbial limits'') will be set and the consequences for an establishment that does not meet them.

There are many possible approaches for setting and using microbial limits. One approach is to set specific quantitative limits for each significant pathogenic microorganism on the basis of a scientific risk assessment, and to use this limit as the basis for excluding from commerce any raw product that exceeds the limit. This is the approach typically taken in the regulation of food additives, chemical contaminants, and physical defects, and provides the most direct and perhaps most effective means of ensuring that standards necessary to protect public health are being met. One difficulty with this approach to pathogenic microorganisms is that the scientific data and understanding concerning the link between specific levels of many pathogens and the risk of foodborne illness that would be needed to set such limits based solely on considerations of public health are not currently available. A second, perhaps more significant difficulty is the fact that the levels of additives and other chemicals generally remain stable, whereas levels of microorganisms can change over time, due to growth and destruction. As explained in a later section of this document, FSIS intends to work with the scientific and public health communities to develop the scientific basis for setting quantitative limits for specific pathogens.

Another approach to pathogen reduction is to set targets for reduction based on what is judged achievable with available science and technology, and to require individual establishments to meet such targets on a consistent basis, by adoption of appropriate process controls. Even with this approach, there are difficult issues concerning the basis upon which such targets should be set. FSIS believes, however, that enough is known today and can be learned during the course of this rulemaking to make this approach viable and very useful in the near term.

Later in this document, FSIS is proposing to set interim targets for pathogen reduction, using as the starting point the current baseline incidence of *Salmonella* contamination of finished carcasses in all raw meat and poultry slaughter operations and in raw ground meat or poultry products, and requiring reductions in *Salmonella* in relation to the current baseline. FSIS believes that significant reductions in the incidence of contamination with this human pathogen are achievable in the relatively near term, and that the process improvements some establishments will have to make to reach the goal will also reduce the levels of other pathogens.

Key to the FSIS strategy for using public health-based microbial limits to reduce pathogens is the recognition that what is scientifically supportable and appropriate will evolve over time. FSIS believes the interim step it is proposing in this new area to target and reduce the incidence of *Salmonella* is feasible and can be effective in the near term, but it is just a first step. As knowledge and methodologies improve, additional pathogens could be targeted, targets could be lowered, and the use of the targets could expand eventually to include their use in some cases as legal standards for products.

FSIS will be working closely in the coming years with the scientific and public health communities, the industry, and public interest groups to consider how microbial limits can best be used to reduce the risk of foodborne illness. Later in this document, FSIS discusses some of the difficult scientific issues that need to be resolved to make the fullest use of microbial limits.

3. *FSIS must make meat and poultry establishments responsible for microbial testing of their products to ensure proper process control and verify achievement of microbial limits.* To

reduce pathogens and protect public health, FSIS believes that microbial testing must become an integral part of the operation of every meat and poultry establishment and that the primary responsibility for testing should rest with the establishment, not FSIS. Over the long term, microbial testing will play a key role in verifying the successful implementation of an establishment's HACCP plan. FSIS also believes that establishments should be responsible for testing their products to verify achievement of any microbial limits that FSIS establishes for regulatory purposes. Later in this document, FSIS is proposing to require daily microbial testing to determine whether, over time, the proposed interim targets for pathogen reduction are being met in all establishments that have slaughter operations or produce raw ground meat or poultry products.

4. *FSIS must foster scientific and technological innovation within the meat and poultry industries to reduce pathogens and the risk of foodborne illness and must remove any unnecessary regulatory obstacles to innovation.* In the past, innovation in the meat and poultry industries has been directed primarily to developing new products and increasing productivity. This innovation has been beneficial because it has responded to consumer demand and need for a diverse, convenient, and economical food supply. One of the principle advantages of holding establishments accountable for meeting public health-driven microbial limits is to provide an incentive for establishments to innovate as they reduce the risk of foodborne illness.

FSIS believes that scientific and technological innovation in the meat and poultry industry will play a key role in meeting the Agency's food safety goal. FSIS will, therefore, be reviewing its current procedures for evaluating and approving new pathogen reduction technologies for use in meat and poultry establishments, and is committed to modifying or eliminating any procedures or requirements that stand as unnecessary obstacles to the prompt implementation by industry of innovations that can reduce the risk of foodborne illness. FSIS invites public comment on how FSIS can improve its program to facilitate beneficial innovation.

5. *FSIS must build the principle of prevention into the operations of meat and poultry establishments and into the FSIS inspection program.* As discussed earlier in this document, food safety can be ensured most effectively and economically by installing systems that prevent problems from occurring rather than relying on end product testing or government inspection to detect and correct problems after they occur. There is wide agreement on this among government and industry officials, consumers and the scientific community. FSIS is proposing to build the principle of prevention into the inspection system by requiring that all meat and poultry establishments adopt and operate under HACCP systems.

6. *FSIS must approach its food safety mission broadly, and address potential hazards that arise throughout the food production and delivery system, including before animals enter FSIS-inspected establishments and after meat and poultry products leave those establishments.* There is wide agreement that ensuring food safety requires taking steps throughout the chain of production, processing, distribution, and sale to prevent hazards and reduce the risk of foodborne illness. Although not the subject of this document, FSIS will work with producers and others to develop and implement ''preharvest'' food safety measures—measures that can be taken on the farm to reduce the risk of harmful contamination of meat and poultry products.

FSIS is also announcing in this document initiatives it plans to undertake in cooperation with the Food and Drug Administration to develop Federal standards that will help ensure the safe handling of meat and poultry products during transportation from FSIS-inspected establishments to the retail level. FSIS and FDA will also work together to encourage adoption and enforcement by State governments of consistent, science-based standards at the retail level.

FSIS believes that its food safety goal can be achieved and legitimate public expectations met only by building a chain of responsibility for food safety, extending all the way from the farm to the consumer.

In the next part of this document, FSIS proposes a set of regulatory changes that it believes will advance the Agency's food safety regulatory strategy.

II. Discussion of Regulatory Proposals

Overview

Because the safety of any meat or poultry product can be positively or adversely affected at virtually every step in the manufacturing process, FSIS is proposing the series of regulatory changes discussed in this section. Collectively, these changes would reduce the incidence of pathogenic microorganisms on meat and poultry products, not only by reducing their numbers at critical points during processing, but also by denying those pathogens that are present the opportunity to grow.

As independent measures, standard operating procedures for sanitation, antimicrobial treatments, and time and temperature requirements for chilling and cooling finished carcasses and parts could have only limited impact on food safety. Together, they can make a significant contribution to reducing pathogenic microorganisms and other contaminants throughout the manufacturing process. These measures are a precursor to HACCP, which ensures process control through carefully selected critical control points. The above-listed measures, discussed at length in II A, have in fact been implemented in many establishments, including many now operating under HACCP systems. By effecting immediate pathogen reduction in meat and poultry products during the period of transition to HACCP, these interdependent measures would address urgent public health needs. Additionally, implementing these measures would introduce into non-HACCP establishments the concept and actuality of process control, which is the essence of HACCP. Each proposed measure can be reasonably expected to constitute a critical control point under most HACCP plans so, while the proposed regulatory provisions may no longer need to be mandated upon implementation of HACCP, establishments would likely retain them as critical elements of process control.

The second component of this three-part regulatory package, the microbiological testing program (discussed under II B), would also be implemented during the transition to HACCP. It, too, is integral to the regulatory strategy, because microbial testing will establish a tangible, achievable, measurable target: a reduction in the incidence of *Salmonella* in raw product. As with the near-term interventions discussed above, the microbial testing program would effect pathogen reduction almost immediately upon implementation. As is the case with the near-term interventions, microbial testing can be expected to constitute an element of process control under HACCP.

The third component of this three-part regulatory package is HACCP (discussed under III C). As indicated earlier, the interim measures which, as proposed, would be implemented during the transition to HACCP would likely continue under HACCP as elements of process control, selected on

the basis of each establishment's hazard analysis.

The proposed sanitation SOP's, antimicrobial treatment, cooling, and microbial testing requirements are compatible with and establish important parts of the foundation for establishments' subsequent adoption of HACCP procedures. It is expected that HACCP controls will give establishments the flexibility to meet the objectives reflected in FSIS's existing requirements for meat and poultry products. Once HACCP systems are integrated fully into all establishments, many existing regulations may be redundant. Anticipating the implementation of HACCP proposed in this document, FSIS has initiated a review of existing regulations, with the intention of removing those no longer needed, as well as of ensuring that regulations that remain are sufficiently flexible to be HACCP-compatible. FSIS invites comment on which regulations should be eliminated or modified. Even now, it may be possible to identify means to achieving prescribed regulatory ends that are as effective as the means set forth in current regulations—that are, in other words, ''equivalent'' to provisions set forth in regulations. FSIS invites comment on specific regulations for which such performance standards might be appropriate, either immediately or upon implementation of HACCP.

A. Transition to HACCP

The following is a discussion of regulations being proposed which, together, are intended to reduce significantly the level and frequency of consumers' exposure to foodborne illness associated with pathogenic microorganisms and other biological, chemical, and physical hazards in meat and poultry products.

The transitional regulations proposed in this document would be made effective 90 days after publication of the final rule (near-term initiatives). The proposed HACCP requirements would be implemented in phases during the three years following the publication of the final rule. As noted above, the near-term initiatives are designed to reduce the level and frequency of consumers' exposure to pathogenic microorganisms now, pending the more comprehensive controls that will be in place in each establishment under the proposed HACCP regulations.

The proposed regulations, roughly in order of their sequence in slaughter and processing operations, are as follows:

- A requirement that all federally inspected establishments develop and adhere to written standard operating procedures (SOP's) specifically relating to direct contamination or adulteration of product;
- A requirement that slaughter establishments use an antimicrobial treatment on all carcasses;
- A requirement to meet specific time requirements for chilling and cooling of all finished carcasses and parts;
- A requirement that certain raw product be tested for *Salmonella,* a representative pathogen, and that establishments achieve targeted reductions in the incidence of *Salmonella,* in relation to the current national baseline incidence, in 2 years (discussed under II B, below);
- A requirement that all establishments adopt HACCP systems (discussed under II C, below).

FSIS intends to proceed to final rulemaking on the specific changes proposed in this document as soon as possible. After comments are reviewed and analyzed, if it is determined that some portions of this proposal can be made into final rules sooner than others after the close of the comment period, they will be separated from the other portions so as to not delay regulatory action on this important public health matter.

These proposals reflect ideas and suggestions generated from many people and organizations. Recent events have prompted a beneficial, ongoing dialogue between FSIS and consumer organizations, trade associations, and other Government agencies, among others, as well as among FSIS employees and their bargaining representatives, on what regulatory changes the Agency should undertake. FSIS values and relies greatly on the input from all these sources, and intends to continue this dialogue throughout this rulemaking and in its future regulatory activities.

1. Sanitation Standard Operating Procedures (SOP's)

Need for SOP's

Proper sanitation is an important and integral part of every food process and a fundamental requirement under the law. Insanitary facilities and equipment, and poor food handling and personal hygiene practices among employees create an environment in which pathogens can flourish. The law is quite clear: product produced or held under insanitary conditions is deemed adulterated, without any further showing required by the Government. FSIS inspectors are expressly charged with ensuring that product inspected and passed was in fact produced under sanitary conditions.

FSIS recognizes that current sanitation practices and performances vary widely among the diverse array of plants FSIS regulates. Well-run meat and poultry establishments have tight quality control and sanitation programs, including written sanitation SOP's, premised in large part on the direct and substantial link between the existence of insanitary conditions during production of meat and poultry products and the likelihood that bacteria—including pathogenic bacteria—will contaminate the finished product. Some establishments, however, do not have adequate programs and do not consistently maintain good sanitation. FSIS is nearing completion of its project to conduct unannounced reviews of 1,000 federally inspected meat and poultry establishments. The findings, based on 551 reviews so far, show that 60 percent (820) of 1,340 serious deficiencies were found in sanitation. Poor sanitation is the most frequently observed problem in meat and poultry establishments.

FSIS is proposing to require that all inspected establishments develop written sanitation SOP's to prevent direct contamination or adulteration of product before and during operations. Establishments would be required to maintain daily records to document adherence to the SOP's. The proposed sanitation SOP's would be compatible with the proposed HACCP requirement. Like HACCP, the sanitation SOP's reflect a commitment by establishment management to consistently control operations in the interests of public health. The SOP's demonstrate that establishment owners know their operations and how to keep the facilities and equipment clean. FSIS encourages both innovation and self-reliance in the achievement of good sanitation in all inspected establishments.

Self-reliance is important because identification of sanitation requirements has been viewed by some establishment owners and personnel as the inspector's responsibility. Such establishments often fail to take the initiative to find and remedy insanitary conditions, relying instead on the inspector to find deficiencies.

Mandatory sanitation SOP's are intended to clarify that sanitation is industry's responsibility, not the inspector's. The sanitation SOP's reflect the establishment's commitment to accomplish those activities consistently, independent of the inspector.

Written SOP's would make it easier for FSIS inspectors to perform their proper role of verifying that establishment management is conducting its operations in a sanitary

environment and manner. Failure to adhere to the ''core elements'' of an SOP (the proposed regulatory requirements) would be presumptive evidence of insanitation and enforcement action, where necessary, would be taken. As is now the case, inspectors will not permit an establishment to operate under insanitary conditions. Falsification of records designed to document daily sanitation activities would, in addition to indicating insanitation, be treated as a criminal act subject to prosecution.

As a more efficient tool for ensuring that establishments are carrying out their sanitation responsibilities, sanitation SOP's can provide the basis for improved utilization of FSIS inspectional resources. Sanitation SOP's thus support the transition to HACCP because, under HACCP, FSIS inspectors will be called upon to perform a number of additional safety-related inspectional tasks to verify that HACCP plans are working properly. If less time can be spent ensuring that basic sanitation requirements are being met, more time will be available for these new tasks.

Some plants already have SOP's, take their sanitation responsibilities seriously, and require a relatively modest investment of inspector time to ensure sanitation requirements are met. Other plants do not consistently perform well in the sanitation area and frequently require a substantial investment of inspector time to ensure basic sanitation compliance before daily operations begin.

In plants where procedural requirements are consistently followed and inspectional observations verify that good sanitation is being consistently achieved, FSIS expects that sanitation SOP's will provide the basis for adjusting the manner and frequency of FSIS preoperational sanitation inspection.

FSIS invites comment on the role sanitation SOP's should play in allocating responsibility between establishment employees and FSIS inspectors for preoperational sanitation, including the role FSIS employees should play in authorizing daily startup of operations.

Content of SOP's

Sanitation SOP's would, at a minimum, detail procedures the establishment will conduct to prevent direct contamination or adulteration of product before and during operations. Such procedures would constitute the required, core elements of an SOP. The SOP's would also identify establishment personnel responsible for evaluating the conduct and effectiveness of the sanitation SOP's, and for making corrections when needed. FSIS encourages establishments to incorporate additional sanitation procedures that provide increased assurance that insanitary conditions will be prevented.

Each establishment would maintain a daily record of the actions prescribed in the SOP, and make such records available to Program employees for inspection audit and verification. Records would, at a minimum, record deviations from the core elements of the SOP (the proposed regulatory requirements), along with corrective actions taken in conjunction with the monitoring of daily sanitation activities. Production could not start until the core elements of the sanitation SOP's that are applicable to preoperational sanitation have been completed.

The daily monitoring of the sanitation program by the establishment representative could include microbiological tests, routine organoleptic inspection of areas and equipment, and direct observation of sanitation procedures while being performed by designated employees.

FSIS will provide guidance materials, including examples, on development of sanitation SOP's prior to the implementation of this requirement.

The following are specific practices relating to sanitation that might be included in an SOP:

- Preoperational microbiological testing: Tests for verifying the efficacy of cleaning, sanitizing, and disinfecting procedures. Many establishments also currently perform preoperational microbiological testing for quality control purposes. The technology for preoperational sanitation microbiological testing is readily available and easy to use.
- Disinfection of equipment prior to startup: Some data exist to indicate that equipment should be sanitized immediately prior to the startup of operations.
- Use of an automated hand washer with approved sanitizing solution effective for up to six hours. This has been proven to be an important sanitary practice.
- Handwashing between each carcass in skinning and evisceration operation.
- Cleaning cattle prior to slaughter: Washing and drying, clipping, dehairing, and any other acceptable method to remove dirt, fecal matter and other potential sources of contamination from the exterior of animals before the edible portions of the carcasses are exposed. The hides of animals are a known source of carcass contamination. Feedlot cattle in general and most bovines during the winter and ''mud season'' carry heavy loads of mud, fecal material and bacterial contamination on the hide. Sanitary removal of the hide under these conditions is very difficult. One method to control this source of contamination is washing animals prior to slaughter. Another possibility is clipping the hair over the areas where opening cuts will be made and sanitizing the hide prior to cutting. Yet another procedure being tested is the complete removal of hair from the hide using a chemical hair remover (depilatory).

The Agency has been asked to consider making mandatory certain GMP's for sanitary slaughter by, among others, the American Meat Institute. The Agency is requesting comments on whether GMP's or other sanitation practices should be made mandatory elements of the sanitation SOP.

The adoption of HACCP systems by establishments would not replace the need for establishments to maintain sanitation SOP's. The proposed HACCP regulations require sanitation SOP's as a prerequisite to a HACCP plan. Sanitation activities that directly affect the control of a processing hazard would be determined according to the criteria discussed in the HACCP portion of this document, and would, where appropriate, be identified as critical control points in individual HACCP plans. Sanitation activities not identified as critical control points under HACCP should remain in the sanitation SOP's. Any SOP requirement incorporated into a HACCP plan could be removed from the SOP's for sanitation.

2. Antimicrobial Treatments

This proposed rulemaking would require, for the first time, that slaughtering establishments apply antimicrobial treatments or interventions to livestock and poultry carcasses. Under the proposal, any one or more of the treatments would have to be applied prior to the chilling or cooling operation. Mandating antimicrobial treatments is a new approach for FSIS. It reflects the judgment that, at least until significant progress is made in reducing or eliminating the presence of pathogenic microorganisms in livestock and poultry at the preharvest stage and in sanitary dressing techniques and practices, some amount of contamination of beef and poultry carcasses with pathogenic microorganisms is likely to occur—even in establishments that attempt to follow the best current practices. To reduce the food safety hazard posed by such pathogens, establishments should be

required to take affirmative measures to reduce or eliminate contamination.

One concern regarding the use of antimicrobial treatments is that such treatments will be relied on as a substitute for careful sanitary dressing techniques which provide the best opportunity to prevent contamination from occurring in the establishment. Other concerns are that some treatments are ineffective at least for certain organisms, and certain treatments, such as carcass washes or soaks, might make matters worse by spreading contamination and can cause economic adulteration.

FSIS agrees that antimicrobial treatments must not be allowed to substitute for careful sanitary dressing procedures, and that any interventions must be effective and not result in economic adulteration. FSIS also agrees that no one treatment will be effective for all pathogens of possible public health concern. FSIS believes that the best way to prevent harmful contamination of meat and poultry products is by adopting multiple approaches throughout production, slaughter, and processing that will contribute to preventing or reducing the likelihood and degree of microbial contamination, especially by pathogens.

FSIS believes that mandating at least one antimicrobial treatment prior to the chilling process is an integral part—but only one part—of the strategy for reducing pathogens on meat and poultry proposed in this document. Product not properly treated with at least one antimicrobial treatment would be retained; the Inspector in Charge would determine its disposition. FSIS invites public comment on this approach, as well as on the issues raised in the discussion below concerning what treatments are effective and appropriate.

Past and Current Agency Policy

Despite establishment's best efforts to reduce or eliminate contamination during slaughter and dressing procedures, livestock and poultry carcasses still may harbor pathogenic microorganisms. The sources of these organisms, most of which are associated with the living livestock and poultry, are not fully understood, and fully effective preharvest preventive measures, while under study, are not currently available. Thus, introduction of pathogenic microorganisms into establishments along with the animals cannot be absolutely prevented at this time. The use of the best slaughter and sanitary dressing procedures and technologies can reduce the likelihood that product will be contaminated by these invisible pathogens, but they cannot guarantee the absence of pathogenic bacteria on raw meat or poultry product.

FSIS recognizes that the technologies now available for reducing bacterial contamination on raw carcasses are limited. Indeed, the inspection regulations currently have no listings for antimicrobial agents as such. However, FSIS has over the years permitted a number of such treatments to be used in inspected establishments on a case-by-case basis, and is proposing to include some of these in the regulations through this rulemaking. Some currently available treatment methods are described below.

New antimicrobial procedures, including variations on those listed below, will be approved for use by FSIS to meet the proposed requirement for an antimicrobial treatment, provided data are submitted demonstrating they are safe and effective for that purpose. Current interventions generally provide at least a one order of magnitude (i.e., a 90-percent) reduction in the numbers of bacteria of concern on treated carcasses.

Antimicrobial treatments are interventions that decrease microorganisms present on the surfaces of meat and poultry carcasses. Antimicrobial treatments are not designed to compensate for sloppy sanitary dressing procedures on the slaughter floor, and under this proposal, will not be permitted to be used for that purpose.

Thus, the proposed use of antimicrobial treatments does not imply a change in current FSIS policy regarding removal of physical contaminants from meat and poultry carcasses. Fecal, ingesta, or milk contamination on cattle carcasses must be removed by trimming. Wash/trim studies are underway to determine the best way to remove these visible contaminants. Public comment and discussion, including peer review, of the data from these studies will be solicited and reviewed as part of the Agency's evaluation and decisionmaking process on this issue.

FSIS policy concerning visible contaminants on poultry continues to require carcasses to be free of fecal contamination before entering the chillers. The process control program set forth in the current regulations provides Finished Product Standards (FPS) for poultry where feces are one of the ''nonconformances'' that are summed with other nonconformances to determine compliance with the standard (9 CFR 381.76). This is only a measure of the presence of this nonconformance, not a tolerance. Finished poultry carcasses are subject to the same requirements as are finished livestock carcasses, with no visible fecal matter permitted. Because of confusion on this point, FSIS is proposing to remove feces from the FPS for poultry to make clear the current policy that there is no tolerance for feces.

The Agency's proposal to codify the zero tolerance policy for fecal contamination was one of a number of recently proposed changes to its poultry inspection regulations, designed primarily to address concerns about pathogens (July 13, 1994, 59 FR 35639). The proposal drew more than 400 comments. Although many critical comments were received, a great majority of the comments on point supported the use of antimicrobial treatments and removal of feces from the Finished Product Standards. Because these two elements of the July 13 proposal are incorporated in this proposal, comments are again being solicited. This does not, however, preclude completion of the July rulemaking on these two issues and the issuance of final rules based on that proposal.

One part of the July proposal that was criticized in the comments is the requirement that the antimicrobial treatment be limited to application prior to the chilling or cooling system. Some commenters indicated that certain antimicrobial treatments for use in the chilling or cooling systems are more effective than treatments applied before this point. Additionally, some held that certain post-chill treatments, such as irradiation, may provide a more effective treatment option. FSIS's intent was, and is, that poultry entering chill tanks be as clean as possible. However, FSIS invites comments on whether mandated antimicrobial treatments should be restricted to pre-chill application, as proposed above.

Irradiation is another issue related to this proposal on antimicrobial treatments. Irradiation is statutorily defined as a ''food additive'' under the Federal Food, Drug, and Cosmetic Act (FFDCA) and thus its safety is evaluated by FDA, which must approve its use as a food additive in a regulation specifying safe and lawful conditions of use. FDA has approved irradiation for use in controlling foodborne pathogens on uncooked poultry (21 CFR 179.26), and FSIS has promulgated regulations under the PPIA specifying inspection requirements for establishments using that process (9 CFR 181.149). FDA currently is considering a petition to permit use of irradiation to control pathogens on uncooked meat. Irradiation is not being considered an

antimicrobial treatment for purposes of this proposal because irradiation facilities are to date extrinsic, stand-alone operations that cannot easily be integrated into a slaughter operation—the focus of the present effort. Furthermore, although irradiation has been shown to be a highly effective pathogen control mechanism, it is a capital-intensive process largely unavailable to most inspected slaughter establishments. Notwithstanding these considerations, firms would be able to use irradiation on raw poultry under existing regulations, in addition to the antimicrobial treatments now being proposed.

Approved Antimicrobial Treatments

A number of methods for reducing the number of bacteria that may be on carcasses have been suggested, e.g., exposing the carcass to hot water, chemical sanitizers, such as chlorine or trisodium phosphate (TSP), and short chain food grade acids, such as lactic, acetic, and citric acids.

Antimicrobial treatments currently permitted by FSIS are techniques involving the rinsing of carcasses with a wash or spray, normally using either hot water or a solution of water and a substance approved by FSIS for that use on the basis that it has been found to be effective and its use is consistent with applicable FDA regulations governing food additives. Some mechanical process modifications currently in use have been shown to enhance the results of rinsing procedures. Countercurrent scald tanks with a postscale spray have been shown to be effective in reducing bacterial levels on poultry carcasses.

Equipment and utensils used in preparing or handling meat and poultry products in inspected establishments are subject to inspection to ensure that their use will not result in adulteration or misbranding of the finished product. To promote efficiency and uniformity in this element of FSIS's inspection duties, FSIS reviews newly developed equipment and utensils intended for use in inspected establishments and publishes a listing of equipment and utensils found to be acceptable for that use (9 CFR 380.5, 381.53). Establishments and other manufacturers of mechanical devices designed for antimicrobial treatments, such as scalding tanks and spray cabinets and devices, must obtain approval of their equipment from the Facilities, Equipment and Sanitation Division, Science and Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington DC 20250. A copy of the current list of approved equipment and utensils also is available from that office.

The use of an antimicrobial treatment on raw meat and poultry carcasses would reduce the levels of bacteria on the product, but it would not eliminate the need for continued careful handling of those products before and after the antimicrobial treatment. The following are available antimicrobial treatments that FSIS tentatively concludes could satisfy its proposed requirements for a mandatory antimicrobial treatment. FSIS invites comment on each of these.

(a) *Hot water.* Hot potable water or steam may be used to reduce microbiological counts on meat and poultry. Washing carcasses with hot water has been shown to be effective in reducing the level of bacteria on carcass surfaces.

The decontamination of carcasses using hot water has a number of advantages. These include: (1) reliable reduction of contaminants, (2) removal of loose extraneous material, (3) no impairment of meat properties, (4) no chemical reaction with equipment, such as the corrosive effects associated with acetic acid, (5) no disposal problems, and (6) readily available and easily accomplished.

Disadvantages with hot water sprays include: (1) the need for greater pumping pressures, (2) less recoverable heat energy from the outlet water steam, (3) the likelihood of nozzle blockage if water is recirculated, and (4) the production of mist which condenses on surfaces in the vicinity of the cabinet if baffles are not used.

Scientific studies over the course of the past twenty years have investigated whether the use of hot water (74°–95°C, 165°–201°F) instead of the commonly used lower water temperatures (30°–35°C, 85°–95°F) can reduce the general microflora of aerobic mesophiles present on the carcass, including members of the family Enterobacteriaceae. This taxonomic group includes some of the most important foodborne pathogens. Hot water rinses have been shown to be effective against a number of foodborne pathogens including *Escherichia coli* O157:H7, *Salmonella, Yersinia enterocolitica,* and *Listeria monocytogenes.* Quantitative studies assessing the impact of hot water treatment on the survival of *E. coli* O157:H7 have suggested that it can reduce the levels present on the carcasses by 84–99.9 percent, as well as the number of contaminated carcasses. Other studies with *E. coli* biotype 1 (*E. coli* O157:H7 is one of hundreds of *E. coli* serovars) have indicated that hot water can reduce levels by 99–99.9 percent.

The effects of hot water washing are dependent on two separate mechanisms. The first is simply the physical washing action of the rinsing. This can account for a significant portion of the overall effect, particularly if the bacteria are only loosely attached to the carcass surface. In addition, the thermal effects of the elevated temperatures produce some degree of heat inactivation. As with any thermal processing, the extent of the inactivation will be directly proportional to both the duration and temperature of the heating material (i.e., water temperature). A hot water rinse can achieve up to a 99.9 percent (3 log) decrease in the levels of various pathogenic and non-pathogenic bacteria. It potentially can achieve up to a 99.9 percent reduction in *E. coli* O157:H7.

Hot water sprays are most effective when applied in a manner that raises the water film on the surface of the carcass (surface temperature of the carcass) to 82°C (180°F) for 10 seconds. Exposure of beef carcasses to 80°C (176°F) water results in a greying of the meat surfaces; however, the color returns to its normal appearance after chilling. When the carcass surface is exposed to 82°C (180°F) for more than 20 seconds, tissue discoloration becomes permanent.

Researchers have tested the effectiveness of hot water using sprays or dips and using decontamination cabinets, with hot water only and with chemical sanitizers.

One study found that treating beef carcasses with a steam and hot water spray at 176°F–205°F (80°C–96°C) for 2 minutes, sprayed from one foot (25 cm.), lowered bacterial numbers. A volume of 18.9 liters of water was sprayed for each carcass. Some discoloration of the carcass surface occurred initially, but normal color returned after cooling for 24 hours.

Another study found a hot water treatment of beef and mutton samples inoculated with *E. coli* more effective in reducing bacterial numbers than a naked flame, steam chamber, steam ejection, or washing with water at 37°C (99°F). When hot water temperatures were below 60°C (140°F), no significant color change was noted. Above 85°C (185°F), the color change was marked and permanent. Permanent color changes of the surface tissues caused by using water at 95°C (203°F) for three minutes did not extend more than about 0.5 mm below the surface. Temperatures of 70°C (158°F) and above gave at least a two log (99 percent) reduction of inoculated *E. coli* on samples.

The hot water spray cabinet used on lamb carcasses had water leaving the nozzles at 95°C, but the temperature of the water reaching the carcass could not be raised above 74°C (165°F). They were able to obtain a 99 percent decrease in inoculated *E. coli* at all sites when sheep carcasses were immersed in 80°C (176°F) water for 10 seconds. Immersion for 30 seconds gave little extra kill of inoculated bacteria. In-plant immersion tests on carcasses that had not been inoculated showed a 98 percent reduction in bacterial numbers.

Researchers have found that pouring hot water at 169°F (77°C) on beef (tissue slices) and mutton (carcass) samples for 10 seconds destroyed more than 99 percent of *E. coli* and *Salmonella* inoculated ($10^{6.5}$/cm²) onto the samples. Tissues surfaces were not permanently discolored. When beef slices (2.5 cm thick) swabbed with bacterial culture were exposed to hot water (60°, 65°, 70°, 80°, 90°C) for intervals of 10, 30, 60, and 120 seconds, it was found that the time of exposure was not a factor, but a progressive decrease in *E. coli* counts from $>10^1$ at 60°C to $>10^4$ at 90°C was noted. Coliform and aerobic mesophilic bacteria counts on six naturally contaminated sheep carcasses were reduced from 100 cells/cm² to below detectable limits and 8,500 to 310 cells/cm² respectively.

A 1979 study applied cold water (16°C, 60°F)(<14 kg/cm²), hot water 76°C–80°C [168°C–176°F])(14 kg/cm²), and steam (95°C) to previously frozen beef plate strips. Treatment with cold water alone reduced the counts by about one log. Steam alone only reduced the count by 0.06 log. Initial reduction in counts by hot water alone was 2.0 log. Samples held at 3.3°C were cultured for several days after treatment. After an initial lag phase of less than a day for samples treated with cold water or steam, the rates of bacterial growth were greater on the treated samples than on untreated controls. By the fifth day the aerobic plate counts for steam and cold water treated samples exceeded the aerobic plate count on the control samples. Presumably this was due to the greater surface moisture from the treatment. The rate of bacterial growth on samples treated with hot water was similar to that on controls, but the initial 2-log difference was maintained through 12 days of storage resulting in nearly 5 additional days for counts to reach 10^8/cm².

A 1981 study reported that lamb carcasses sprayed with hot water at temperatures >169°F (77°C) caused significant decreases (1.0 $\log_{10}$/cm²) in APC. As temperature was increased the reduction in bacterial numbers observed by spray washing was increased.

Another researcher used a deluge method instead of conventional pressure spraying. Advantages cited include: construction simplicity, cheaper running cost, and greater reduction in bacteria. However, unlike spray decontamination, coverage of the abdominal and thoracic cavities was only about 65 percent. He found a significant (<0.05) linear relation between the log reduction in inoculated *E. coli* and average water film temperature which varied with exposure time immediately after treatment. Longer exposure (20 sec vs 10 sec) produced significantly greater reduction at higher temperatures (44.5°, 66.0°, 74.2°, 83.5°C). There was no significant growth of *E. coli* between 24 and 48 hours, which is consistent with the findings of several other researchers. After chilling for 48 hours, sides exposed to 83.5°C had a slight and apparently permanent bleaching of the fat and meat tissue in the area of the upper thoracic cavity.

In a 1993 study, carcasses were sprayed with 2 liters of hot (95°C) water for 40 seconds with the intent of raising the meat surface temperature to 82°C for 10 seconds before final wash and after final wash. The apparatus was designed to raise the temperature within 30 seconds and maintain it at 82°C for 10 seconds. Culture samples taken from hot water-treated carcasses before final wash had a mean $\log_{10}$/cm² of 1.1 while controls had $\log_{10}$/cm² of 2.4. Culture samples taken from hot water-treated carcasses after the final wash had a mean $\log_{10}$/cm² of 1.5 while controls had $\log_{10}$/cm² of 2.3. It was unclear why a greater reduction in bacterial numbers occurred when carcasses were sprayed with hot water before the final carcass rinse. A 15–20 minute elapsed time between hot water and final wash may have allowed more bacterial attachment to take place. The volume of the spray and the size of droplets were found to have a profound effect on the temperature of the water contacting the carcass surface.

In view of this research, FSIS is proposing that hot water treatments used to meet the intent of this regulation be applied such that the temperature of the water at the surface of the carcass is ≥ 165°F (≥ 74°C) for ≥ 10 seconds. If applied by a spray, this is likely to require that the water be heated to a somewhat higher temperature. The hot water would have to contact all carcass surfaces. Other combinations of time and temperature of hot water also may be effective. FSIS would like comments on this point.

FSIS considers the final beef carcass wash to be an appropriate point at which to apply hot water as an antimicrobial treatment. The final carcass wash occurs at the end of the slaughter and dressing process, after trimming and FSIS postmortem inspection is completed. The final carcass wash is usually the last step in the dressing process before the carcass enters the cooler for chilling. The final carcass wash removes blood, bone dust, hair, dirt, and other accidental contamination. On November 1, 1994, FSIS announced that hot water rinses will be allowed at the final beef carcass wash without prior approval. An establishment wishing to apply hot water to beef carcasses at the final wash no longer must obtain prior approval by FSIS. However, FSIS notes that a hot water wash used pre-evisceration might also meet the intent of this regulation and therefore has the potential advantage of removing/destroying bacteria before they have had time to become tightly attached to carcass tissues. FSIS invites comments on whether the use of hot water wash to satisfy the proposed requirement of an antimicrobial treatment should be limited to the final carcass wash or should be permitted at other stages of the slaughter and dressing process.

A list of studies on various methods of applying hot water to meat and poultry carcasses is on file in the FSIS Docket Clerk's office, and is available from the Director, Slaughter Inspection Standards and Procedures Division, FSIS, U.S. Department of Agriculture, Washington, DC 20250. FSIS welcomes additional data on the effectiveness of hot water as an antimicrobial treatment, especially regarding the effectiveness of varying temperatures and times of exposure.

(b) *Lactic, acetic, and citric acid solution sprays.*

Lactic, acetic and citric acids are weak acids that have long been consumed by humans in a variety of foods. They occur naturally (e.g., citric acid in limes), have been added in the processing of a broad variety of foods (e.g. acetic acid in mayonnaise), and develop in the fermentation of foods (e.g., lactic acid in cheese).

FDA lists acetic acid as Generally Recognized As Safe (GRAS) as a direct food substance in 21 CFR 184.1005 if used at levels not exceeding current good manufacturing practice (CGMP). The acetic acid listing specifies that the CGMP results in a maximum level in meat of 0.6 percent as served. While the use of acetic acid on fresh meat was not reviewed by the Select Committee on GRAS Substances in reaching its

conclusion on the safety of food use of acetic acid, FDA believes that use of acetic acid as proposed in this rule will result in residual levels on product ''as served'' below the most restricted use levels specified in § 184.1005 for acetic acid (FDA November 29, 1982), 0.15 percent for ''all other food categories.''

Lactic acid is approved as GRAS at 21 CFR 184.1061 with no limitations other than good manufacturing practice. In addition, lactic acid is listed for use as an antimicrobial agent in foods, also at a level not to exceed good manufacturing practice.

Citric acid is listed for multiple purpose use in 21 CFR 182.1033, when used in accordance with good manufacturing practices.

In addition, sections 318.7(c)(4) and 381.147(f)(4) of the regulations (9 CFR 318.7(c)(4) and 381.147(f)(4)) currently allow the use of acetic, lactic, and citric acids as acceptable ingredients in various meat and poultry products when used as acidifiers or as esterifiers in margarine. Citric acid may also be used as an anticoagulant, a flavoring agent, and a synergist at various levels in various meat and poultry food products. Citric acid is acceptable as a curing accelerator to speed up color fixing or preserve color during storage of cured pork and beef cuts and cured comminuted meat food products.

In 1990, FSIS determined that lactic, acetic and citric acids can be safely and effectively used as antimicrobial treatments on meat and poultry carcasses and by-products during slaughter and dressing procedures. That determination was based on an extensive review of the scientific literature on methods of reduction of bacteria on meat surfaces.

During the past twenty years the use of organic acid rinses to reduce spoilage and pathogenic microorganisms on foods has been studied extensively. Numerous researchers have demonstrated that organic acid rinses can produce a significant reduction in bacterial levels on the surfaces of meat and poultry. Although most of these studies have been conducted under laboratory conditions, there have been some studies that have specifically assessed the efficacy of these antimicrobial systems under production conditions. Also, some of the laboratory research has been conducted under simulated in-plant conditions.

The results achieved in the various research trials have not been unequivocal, in part because the effectiveness of the compounds is dependent on their interactions with a number of other factors. Some of the factors that have been identified include (1) pre- versus post-rigor tissue, (2) pre-washing prior to treatment, (3) tissue type, (4) method for acid delivery, (5) droplet size, (6) flow rate/pressure, (7) temperature, (8) pH, (9) contact time, (10) bacterial species, (11) type of acid, (12) buffering capacity, and (13) moisture content. Differences in study design, especially factors such as methods used to collect tissue samples and analyze for bacterial species or the preadaptation of bacterial cells to an acid environment, affect results. Interpretation of research results can also be confounded by difficulty in obtaining valid microbiological data because of large carcass to carcass variations, as well as differences in microflora associated with different slaughter facilities, carcasses, and sample sites on individual carcasses.

The literature suggests it is important to lower the pH of the meat surface if bacteria are to be controlled effectively by using an organic acid. Most organic acids are effective only at low pH values of pH 5.5. Apparently the anion exerts some effect on bacteria at pH values of pH 5.5. The pH affects the extent of dissociation. Undissociated weak acids are more effective than the dissociated form and dissociate to produce acidification of the cell interior.

Overall, the available scientific data indicate that washing of carcasses with organic rinses or sprays can achieve a 90–99.9 percent reduction in levels of spoilage bacteria (e.g., *Pseudomonas fluorescens*) though in some cases the reductions were not statistically significant and in others no improvement was noted. In addition, acid sprays and dips have also been shown to decrease the levels of specific pathogens, as well as the incidence of carcasses that are positive for specific pathogens. This includes activity against *Salmonella* spp., *Staphylococcus aureus, Campylobacter jejeuni, Yersina enterocolitica,* and *Listeria monocytogenes.* However, these techniques do not and cannot be expected to completely inactivate or eliminate pathogens.

One of the bacterial species that appears to be among the more resistant to the effects of organic acids is *E. coli* O157:H7. A number of investigators have found that O157:H7 has a relatively high acid tolerance. Again, the extent of inactivation achieved with *E. coli* O157:H7 has varied among the various studies. For example, one researcher found that *E. coli* O157:H7 reductions were similar to those observed for *Salmonella* spp. and *Listeria monocytogenes,* with up to a 99.9 percent reduction in the levels of all three bacteria from inoculated tissues and concluded that an acetic acid carcass sanitizer could be used as an effective method to control these bacterial pathogens. Conversely, another reported that up to 1.5 percent acid treatments did not appreciably reduce *E. coli* O157:H7, whether at 20° or 55°C and ''was of little value in disinfecting beef of *E. coli* O157.'' It has been reported that there are differences among *E. coli* O157:H7 isolates in relation to their acid tolerances. These investigators also found that inactivation was dependent on acid concentration (5 percent gave greatest reductions), and tissue type (reductions greater on adipose tissue than lean). Some investigators have suggested that lactic acid is more effective than acetic or citric acid against *E. coli.* It has been suggested that the primary determinants of effectiveness were the pH achieved at the surface of the carcass and the corresponding period of exposure.

Organic acids apparently are more effective when applied as soon after slaughter as feasible, and when they are at elevated temperatures (53°–55°C). The bacteria found on a carcass soon after slaughter are believed to be present in a water-film on the surface and, therefore, are relatively easy to remove, contrasted with bacteria that have become attached to the carcass surface itself by the time chilling is complete and are therefore more difficult to remove.

Overall, organic acid rinses appear to be a generally effective antimicrobial intervention that have several distinct advantages. Specifically, the advantages include: (1) the technique can achieve up to a 99.9 percent (3 log) decrease in the levels of specific pathogenic and non-pathogenic bacteria; (2) the effectiveness of the application can be readily monitored; (3) the technology can be implemented through a relatively straightforward modification of existing equipment; and (4) this is a process for which there are no apparent ''tradeoffs'' in relation to other risks or negative attributes (e.g., the presence of residues or the need to eliminate environmentally sensitive byproducts). The primary disadvantage is that the effectiveness of acetic acid rinses against *E. coli* O157:H7 is not as great as against other pathogens, and at least some studies indicate that these rinses may not achieve the results desired.

In 1992, FSIS issued a directive (FSIS Directive 6340.1, 11/24/92) that provided guidance to FSIS employees on conditions of use, and how to evaluate and respond to livestock establishments' requests for approval of pre-evisceration carcass spray systems using an acid spray to reduce the

microbial population and retard further microbial growth on livestock carcasses. For beef carcasses, FSIS also recently authorized establishments to use acetic, citric, or lactic acids on inspected and passed carcasses before chilling in conjunction with the final wash without prior FSIS approval on an establishment-by-establishment basis.

FSIS is proposing that, to satisfy the proposed requirement for at least one antimicrobial treatment, acetic, lactic, or citric acid could be applied to carcass surfaces prior to entering the cooler. FSIS is preparing to propose in a separate rulemaking that these organic acids be listed, as approved antimicrobial agents, in 9 CFR 318.7 and 381.147 for livestock and poultry uses, respectively, in a solution of 1.5–2.5 percent concentration and in such a fashion that all carcass surfaces would be contacted.

FSIS invites comments on whether the use of these acids to satisfy the program requirements for an antimicrobial treatment should be limited to post-inspection application in conjunction with the final carcass wash or should be permitted at earlier stages of the slaughter and dressing process, such as after skinning but before evisceration and completion of postmortem inspection by FSIS inspectors, or during chilling. FSIS also invites comment on whether organic acid sprays should be considered an acceptable antimicrobial treatment in beef slaughter establishments in light of the reported acid-resistance of *E. coli* O157:H7, which is a pathogen of particular public health concern in beef.

A list of studies on the application of organic acids on meat carcasses is on file with the FSIS Docket Clerk and may be obtained from the Director, Slaughter Inspection Standards and Procedures Division, FSIS, U.S. Department of Agriculture, Washington, DC 20250.

(c) *Trisodium phosphate (TSP).* The application of TSP to raw poultry carcasses by spraying or dipping with a solution of water and food grade TSP was recently approved by FSIS. Trisodium phosphate (TSP) is listed in the FDA regulations as GRAS for multiple purpose use, in accordance with good manufacturing practices. FDA has affirmed that application of TSP to raw poultry carcasses is consistent with the GRAS listing for TSP. Additionally, TSP (sodium phosphate, tribasic) is listed in the Food Chemicals Codex III (1981).

FSIS has granted interim approval for use of TSP at pre-chill and post-chill locations, and has begun rulemaking procedures to include this compound in 9 CFR 381.147(f)(4), Table 1, under the new class of substances to be called ''antimicrobial agents'' (59 FR 551). TSP reduces bacterial levels, including pathogenic bacteria, on raw poultry carcasses when applied by spraying or dipping the raw poultry carcasses for up to 15 seconds post-chill or for up to 30 seconds pre-chill with an 8–12 percent solution of TSP in water. TSP may be applied to raw chilled poultry as a solution maintained at 45°F–55°F, and to raw poultry as a solution maintained at 65°F–85°F.

Industry, university, and Agriculture Research Service studies demonstrate TSP induced reductions in carcass *Salmonella* levels ranging from 90 to >99.9 percent (1.2 to 8.3 $\log_{10}$). The higher *Salmonella* reductions were associated with pre-chill TSP applications. Mean carcass *Salmonella* prevalence was reduced from up to 23 percent to approximately 1 percent. Industry studies demonstrate median reductions in carcass *Enterobacteriaceae* and *E. coli* levels of approximately 99.5 percent (2.5 $\log_{10}$). In a study conducted by an independent laboratory, *Campylobacter* average prevalence was reduced from 100 percent to 30 percent with mean numerical reductions of >99.9 percent (4 $\log_{10}$) following TSP application to raw, unchilled poultry carcasses. TSP application to raw poultry, under the above stated time, concentration, and temperature conditions of use, therefore, causes statistically significant reductions in these most common gram negative pathogens associated with raw poultry.

As part of the poultry chilling process, poultry carcasses may gain moisture up to the levels permitted in 9 CFR 381.66(d). Poultry establishments using TSP are not exempted from the moisture absorption and retention limits contained in 9 CFR 381.66(d). To preclude the potential for economic adulteration of poultry carcasses as a result of TSP treatments, federally inspected establishments applying TSP to raw poultry carcasses will include the TSP application in their washing, chilling, and draining method as outlined in 9 CFR 381.66(d)(8).

Commercial use of TSP has only recently begun in some poultry establishments. It is not yet widely used. A commercial study investigating the efficacy of TSP in reducing bacterial levels on beef carcasses is in progress.

Federally inspected establishments using TSP as an antimicrobial agent on raw poultry have consistently met local and State effluent phosphate discharge requirements by making minor modifications to their effluent flocculation methods.

FSIS is proposing to permit TSP to be applied to poultry carcass surfaces at any point prior to entering the chiller as one means to meet the proposed requirement for an antimicrobial treatment. FSIS intends to propose in another rulemaking a regulation to list TSP in part 381.147(f)(4), Table 1, as an approved antimicrobial agent. TSP would be applied in a solution of 8–12 percent concentration in such a fashion that all carcass surfaces would be contacted.

A list of studies done on the application of TSP to poultry carcasses is on file in the FSIS Docket Clerk's office, and is available from the Director, Slaughter Inspection Standards Division, FSIS, U.S. Department of Agriculture, Washington, DC 20250.

(d) *Chlorinated water.* The washing of carcasses with chlorinated water to reduce the amount of spoilage and pathogenic microorganisms on carcasses is a longtime practice in the poultry industry. As early as 1951, researchers noted the effectiveness of in-plant chlorination in lowering bacteria counts on product, increasing shelf life, reducing odors in the establishment, and reducing slime on equipment.

Chlorine is now used in most poultry establishments, primarily in chill water, to minimize bacterial cross-contamination and as an effective sanitizing agent on facilities and equipment, usually at FSIS-sanctioned levels of 20 to 50 parts per million (ppm) available chlorine.

A FSIS study published in 1992 showed significant microbial reductions on raw chicken carcasses and giblets immersed in chlorinated chill water. In this study, the addition of 25 ppm of chlorine in the chill water resulted in a significant decrease in aerobic plate counts, *Enterobacteriaceae*, and *E. coli*. Some reduction also occurred without chlorine in chill water indicating that chilling carcasses in this manner actually reduces the bacterial load on carcasses. The effect on *Salmonella* was a reduction in the amount of cross-contamination. Without chlorine, the percent of carcasses exiting the chiller with *Salmonella* versus the percent going in increased significantly. With the addition of chlorine, the differential was not significant. The conclusion was that chlorine aids in the control of cross-contamination in the chillers.

Chlorinated water has long been recommended for reducing bacteria in poultry processing establishments. In one study 34 ppm chlorine reduced salmonellae in broiler chill water to non-detectable levels, and resulted in significant reductions (10–13 percent) in

the incidence of *Salmonella* on the carcasses.

A 1968 study demonstrated that by incorporating chlorine (20 ppm) into sheep carcass wash water, bacterial numbers were reduced significantly, but usually less than one log. Another study showed increased reductions in bacterial numbers were obtained as the chlorine level in water used to wash lamb carcasses was increased up to 357 ppm. Another researcher observed similar reductions when lamb carcasses were washed with 150 and 250 ppm chlorine. A study in 1977 found that up to $\log_{10}0.7/cm^2$ reduction could be obtained by using water containing 200–250 ppm chlorine to spray beef tissue.

An initial mean reduction of 0.31 log on beef tissue has been achieved by treating it with a 200–250 ppm chlorine wash. FSIS considers the application of chlorine at levels up to 30 ppm on poultry, including giblets and salvaged parts, and in poultry chiller water, to be prior sanctioned under the food additive provisions of the Federal Food, Drug, and Cosmetic Act. The comparable use of chlorine in sprays applied to livestock carcasses is also a practice that has long been permitted by FSIS.

The vast majority of poultry establishments and a growing number of meat establishments apply chlorine solutions during slaughter and processing. To meet the intent of the regulation, FSIS would allow the application of 20–50 ppm chlorine in the final wash for livestock and poultry carcasses.

Some environmental risks have been associated with the use of chlorine, most significantly from the formation of byproducts of chlorine reactions with organic compounds in water. The trihalomethane (THM) byproducts are the current focus of regulation of drinking water chlorination by the Environmental Protection Agency under the Safe Drinking Water Act. It has been reported that there is an association between long-term exposure to chlorinated drinking water and a 9–15 percent higher incidence of human bladder and rectal cancer. The researchers were of the opinion, however, that the public health risks from microbial contamination in unchlorinated water ''greatly exceed'' the risks of possible increased incidence of bladder and rectal cancers.

Because one of the THMs, chloroform, is an animal carcinogen, FSIS contracted with a private firm to perform a quantitative cancer risk assessment on chloroform residues recovered from the fat and skin of whole broiler chickens purchased at retail. Based on this assessment, estimates of additional lifetime cancer risk in the population from consumption of chloroform residues in chicken ranged from two in one billion (2×10^{-9}) to five in 100 million (5×10^{-8}) for fat, and from two in one billion (2×10^{-9}) to four in 100 million (4×10^{-8}) in skin based on estimates of chicken consumption. These are well below the level of one in one million (1×10^{-6}) additional lifetime cancer risk generally considered negligible by EPA and FDA in their regulation of pesticides and other chemicals, such as animal drug residues.

FSIS believes that these extremely small risks are clearly outweighed by the public health benefits of chlorine in reducing microbial contaminants on product. FSIS permits the use of nitrites in cured products on a similar basis; the antimicrobial safety benefits provided consumers by its use greatly outweigh the very small risk posed by possible carcinogenic byproducts.

At the request of FSIS, ARS is studying the possible risks from any mutagens that might be formed with the use of chlorinated poultry chiller water. Early phases of this study indicate only that very low levels of mutagenic compounds are associated with chlorinated poultry chiller water and that they increase as the chlorine levels used increase.

FSIS will continue to monitor closely all data on the safety of chlorine when used on carcasses as an antimicrobial agent, and will continue to reevaluate the risks and benefits associated with approved use.

FSIS invites comments on the risks and benefits of chlorine used to reduce and control microbial levels on meat and poultry products.

Product for Export

Application of antimicrobial treatments under this proposed regulation might interfere with the export of the products. This may be especially true for products from carcasses treated with certain chemicals. For example, Canada limits the use of chlorine on poultry products to a maximum of 20 ppm, and chlorine is not permitted at all in some of the countries of the European Union.

Therefore, so as not to interfere with the export of meat and poultry products, and enable companies to meet the expectations of their customers, FSIS is proposing to exempt from antimicrobial treatment product designated for export only. This exemption would apply only to product being prepared for export to a country which will not accept product exposed to the antimicrobial treatment installed in the establishment under this proposed regulation. Exempted export product must be properly identified, segregated, and labeled. FSIS invites comments on this proposed exemption.

3. Temperature Controls

Temperature is one of the primary factors affecting bacterial multiplication; the lower the temperature, the more slowly the multiplication occurs. Carcass surfaces become contaminated with bacteria during the slaughter and dressing procedures, while carcass interiors remain uncontaminated. Rapid cooling of carcasses prevents the multiplication of pathogenic bacteria on the carcass surface, and thus reduces consumer exposure and risk.

FSIS has concluded that most raw meat and poultry products must be rapidly chilled to 50°F and then maintained at 40°F or below to minimize the risk to public health from pathogens on those products. The technology needed to achieve the proposed chilling standards is readily available and for the most part already installed in establishments. The change being proposed is that appropriate time-temperature controls for handling raw product, already generally adhered to by many establishments, will become mandatory for all establishments.

Accordingly, a new section 318.25 would be added to the meat inspection regulations requiring that establishments cool livestock carcasses and raw meat products so the products reach a temperature of 50°F or below within specified time periods and maintain cooled carcasses and raw meat products at 40°F or below throughout handling, holding, and shipping to other official establishments, with certain exemptions. One exception is for raw product going directly into processing that includes a pathogen-lethal heating step, and thereby results in a ''ready-to-eat'' product. Raw product would be partially exempt from the time-temperature requirements applying to fresh carcasses because when product enters a ready-to-eat process, other time-temperature controls applicable to the raw ingredients would apply. Additionally, the processing treatment required for ready-to-eat products stabilizes the product by killing both pathogens and spoilage bacteria. Another exception to the proposed cooling requirements is for ''hot-boned'' product, that is, muscle tissue removed from the carcass before chilling, which would have to be cooled within 5 hours (meat) or 1.5 hours (poultry) to a surface temperature of 10°C (50°F). Any edible parts removed from the carcass and not to be heat processed directly, e.g., livers, hearts, and heads with cheek meat, must

enter a chiller within 1 hour and chill at the same rate as carcasses.

This proposal also would amend section 381.66 of the poultry regulations so they are substantially consistent with the proposed meat inspection regulations regarding temperature and chilling requirements. Section 381.66 currently requires that all poultry slaughtered and eviscerated in an official establishment be chilled immediately after processing so that the internal temperature is reduced to 40 °F or below within a time period appropriate to the size of the carcass. It further requires that eviscerated poultry to be shipped from the establishment in packaged form be maintained at 40 °F or below, with certain exceptions. Section 381.66 would be amended to include new time/temperatures requirements, to mandate corrective actions when time/temperature controls fail, and to eliminate other provisions inconsistent with those being proposed for meat. FSIS believes the proposed time-temperature cooling requirements for meat are equivalent to those in effect and being proposed for poultry in terms of their public health benefits and are readily attainable under current commercial conditions.

Time-Temperature Requirements

FSIS is proposing that establishments cool the surface of meat carcasses to 50 °F or below within 5 hours and to 40 °F or below within 24 hours from the time that carcasses exit the slaughter floor. This cooling rate is based on the best estimate of what is needed to minimize multiplication of pathogenic organisms and what is achievable in a well-controlled meat establishment. Controlling the surface temperature also ensures that the interior is cooling at a reasonable rate.

Carcasses and raw meat products would be required to be maintained at an internal temperature of 40 °F or below during handling, holding, and shipping. FSIS considered a higher temperature limit because at temperatures below 50 °F, spoilage bacteria generally multiply faster than pathogens. Thus, meat below 50 °F generally will spoil before excessive pathogenic bacterial multiplication can occur. For example, spoilage bacteria, such as *Pseudomonas* spp., *Pediococcus* spp., and *Lactobacillus* spp., not only increase faster than pathogenic bacteria, below 50 °F, but some also form inhibitory compounds. However, FSIS rejected a higher temperature limit and is proposing 40 °F because: (1) The lower temperature provides an additional margin of safety against the multiplication of pathogenic bacteria, (2) 40 °F has long been the maximum temperature recommended, as set forth in Agriculture Handbook No. 412; (3) the U.S. industry generally uses much lower temperatures (e.g., 30 °F (−1.1 °C) to retard spoilage as well); and (4) 40 °F would be the same as the temperature currently required for chilling poultry products (9 CFR 381.66).

Except for hot-boning operations, where muscle tissue is removed from the carcass before cooling, FSIS is not proposing a set time to attain an internal temperature of 40 °F. This is because, when the surface temperature of a product reaches 40 °F within the proposed 24 hours and is maintained at that temperature, the laws of thermodynamics ensure that the interior will cool to a safe temperature within a reasonable time frame. Since carcass weight and composition affect the interior cooling rate, a set time to an internal temperature would be too strict for heavy carcasses and too lenient for light carcasses.

There are additional reasons to use surface temperatures. First, any bacterial pathogens on a fresh carcass are concentrated on its surface. The deep tissue of carcasses, with few exceptions, is sterile. Thus, the control point should be where the potential hazard exists. Second, the surface is the most prudent place to measure temperatures. Probing the deep muscle tissue of carcasses before they are fully cooled could cause a public health problem by injecting any bacterial pathogens on the surface into the sterile warm interior.

Hot-boned product, however, would be controlled by internal temperature. Cutting into the carcass increases the probability of deep tissue contamination due to tears in the muscle facia, flexing, punctures, and additional handling. Therefore, the internal temperature is the critical control point. And, since the integrity of the carcass has been violated, the internal temperature is the appropriate monitoring point.

The proposed cooling rates, holding temperature, and corrective actions specified in the proposed rule are based primarily on the thermodynamics of cooling meat and the effect of temperature on bacterial multiplication. Further information on how these were calculated is available in ''The Scientific Basis for Proposed Time-Temperature Requirements,'' a paper on file in the FSIS Docket Clerk's office and available upon request from Director, Processed Products Inspection Division, FSIS, U.S. Department of Agriculture, Washington, D.C. 20250.

This proposed rule would also require that carcasses and raw meat products reach a temperature of 40 °F or below prior to leaving the establishment. Requiring a temperature of 40 °F or below prior to entering commerce provides added assurance that during transportation the product will be maintained at 40 °F and bacterial multiplication will be restricted. Carcasses or raw meat products are permitted, however, to enter a ready-to-eat process at the establishment, before being cooled to an internal temperature of 40 °F.

Slaughtering establishments would be required to begin cooling raw meat products other than carcasses within 1 hour of removal of the tissues from the carcass. Establishments generally remove raw meat products, such as livers, hearts, heads, and cheek meat, before the carcass exits the slaughter floor. These products have a history of poor microbiological quality because the products are packed in boxes before cooling or are moved to the cooler only after a delay. The requirement that cooling of these products begin within 1 hour of removal from the carcass would reduce the opportunity for pathogenic bacterial multiplication and improve the microbiological quality of these products. The cooling rate proposed for these products is the same as that for the carcass surface—50 °F within 5 hours and 40 °F within 24 hours.

The method used to measure the surface temperature of a carcass or a raw meat product would be at the discretion of the establishment. Pressing the side of a temperature probe against the meat surface is the easiest and most inexpensive method. Because air has low heat capacity relative to meat, this method should give a good estimation of the meat surface temperature. Shielding the probe from room air should increase the measurement accuracy. For shielding, one suggestion is to place two carcasses together and measure the contacting surfaces. Shielding the probe from room air with a food contact material having low heat conductance and capacitance, such as a dry sponge in a plastic bag, after proper sanitizing, would also be effective.

The time-temperature profiles being proposed might be modified for certain raw products if other factors such as dryness or acidity are factored in. Therefore, it is possible that an establishment's designated processing authority could develop alternative time and temperature procedures for cooling, shipping, receiving, and, or holding carcasses and raw meat products that would produce microbial profiles equivalent to or better than those produced under the proposed requirements. The Agency is therefore

proposing to allow use of time and temperature limits equivalent to those specified in the proposed requirements. Any such alternate procedures would, however, be difficult to monitor for regulatory purposes. FSIS welcomes comment on this point.

Written Plan for Meeting Time and Temperature Requirements

Establishments would be required to develop, implement, and place on file a written plan for meeting the time and temperature requirements either prescribed in this proposed rule or in alternative procedures developed by a processing authority. The plan would include the establishment's designated control points, i.e., the points within an establishment's operation where temperatures would be measured; monitoring procedures; records to be kept; standards for the control points, including the cooling rate, holding temperature, and shipping temperature; corrective actions to be followed if deviations occur, including a system for separating and identifying noncomplying product; and, when applicable, the name of the processing authority. The plan would be required to be maintained at the establishment for as long as the plan is being used by the establishment. The plan and monitoring records must be made available to Program employees upon request.

Establishments would be required to monitor and record the maximum temperature of a representative number of carcasses and raw meat products periodically during the establishments' operation, as set forth in their written plan for doing so. The frequency of monitoring temperatures in a day's operation by establishments would vary, depending on the size and type of an establishment's operations. Establishments would include in this written plan the control points and the frequency of measuring the temperatures in a day's operation. Establishments would be required to use temperature measuring devices readable and accurate to 2 °F (0.9 °C). The monitoring records would be maintained for up to 6 months after the temperature measurement, or until such time that may otherwise be specified by the Administrator. Program employees would verify the frequency of temperature measurement to ensure that the establishment's written plan is being followed. Inspection personnel would also measure temperatures at various control points and compare these temperatures with those measured and recorded by the establishment.

Effect on Commercial Meat Manufacturing

Because raw poultry is already subject to chilling regulations, it is expected that this proposed regulation primarily will affect meat establishments.

Present commercial meat manufacturing and distribution practices are diverse. Some establishments slaughter animals, prepare raw meats, and process and ship ready-to-eat products. Others may only slaughter and dress animals, debone meat, or prepare raw meats as ingredients for ready-to-eat products. This proposed rule would cover all official establishments that slaughter, receive, store, transport or otherwise handle carcasses and raw meat products.

The following is a brief discussion of present commercial meat manufacturing and distribution operations and how this proposal would affect those operations.

(a) *Slaughter establishments.* Slaughter establishments receive live animals and produce raw meat. The establishment's task is to remove the animal's hide and viscera in a manner that results in meat with as few bacteria as possible. This task is called ''sanitary dressing.'' After dressing, establishments cool carcasses to retard the multiplication of any pathogenic or spoilage bacteria.

The primary means of cooling is to move the carcass into a cold room where the temperature and air movement reduce carcass temperature. Some establishments use various procedures to enhance carcass cooling. The carcass spray chill method increases the cooling rate through direct heat absorption and enhanced evaporative cooling. The sprayed water directly absorbs some carcass heat on contact then absorbs even more when it evaporates. Spray chilling is also advantageous to the manufacturer in that it reduces the amount of weight lost from the carcass by evaporation. The disadvantage is that the increased surface moisture facilitates multiplication of bacteria.

A related practice is hot-boning, which involves the removal of the meat before the carcass is fully cooled. The advantage of hot-boning is that the meat is reduced to smaller, more easily cooled pieces, and the meat is available for processing sooner than if it were removed only after the carcass is fully cooled. However, hot-boning poses a hazard if exposed warm meat surfaces remain at warm temperatures long enough to allow bacterial multiplication.

This proposal would permit any of these cooling procedures as long as the proposed cooling temperatures and time periods are met.

(b) *Shipping and receiving.* Slaughter establishments may ship meat food products in several forms, such as carcasses, cuts, manufacturing meat, or ground meat. In the past 20 years, the geographic concentration of raw meat processing has made boxed meat the primary form in which raw meat is shipped. Boxed meat is often shipped in 60-pound containers of boneless manufacturing meat, cuts, primal cuts, or subprimal cuts.

However, establishments still ship carcasses and larger containers of manufacturing meat weighing 500 pounds or more.

Processing establishments manufacture raw meat products, ready-to-eat meat products, or both. Processing establishments that are not also slaughter establishments must receive raw meat products from other establishments. This proposed rule would affect such processing establishments by requiring them to ensure that raw product received is at the required internal temperature of 40 °F or below, and to maintain the raw meat product ingredient at that temperature in conformance with the proposed requirements.

This proposed rule would require that establishments cool the carcasses and raw meat products to an internal temperature of 40 °F or below prior to shipping such products to help ensure that, if the products are shipped to other official establishments, the products arrive at the receiving establishments at an internal temperature of 40 °F or below.

The shipping establishment would be required to record the date and time of shipment on the waybill, running slip, conductor's card, shipper's certificate, or any other such papers accompanying a shipment. This is necessary to enable the receiving establishment to determine the number of hours the products have been in shipment.

Compliance with the requirement ends when the raw meat product enters a ready-to-eat process at the establishment or is no longer in the possession or under the control of the establishment. Product in the possession of or under the control of the establishment remains the responsibility of the establishment. Establishments must undertake all reasonable precautions to ensure that such product is maintained as required under the proposed rule, even when it is in a transport vehicle or otherwise not physically at the establishment.

Although this proposal directly affects only FSIS-inspected establishments, FSIS encourages adherence to the proposed time/temperature requirements by all who handle or store raw meat and poultry products. At the end of this preamble, the Agency discusses plans to consider increasing oversight of the commercial handling of meat and poultry at locations outside inspected establishments, including during transportation, distribution and storage to the retail level. FSIS will be considering measures to ensure proper handling and cooking of raw and poultry products throughout the food safety continuum.

B. Microbial Testing; Interim Pathogen Reduction Targets

As discussed earlier, the centerpiece of the FSIS food safety strategy is to articulate what constitutes an acceptable level of food safety performance by a meat or poultry establishment and hold the establishment accountable for achieving that level of performance. In the case of pathogenic microorganisms on raw product, this means establishing targets, guidelines, or standards and requiring establishments to conduct regular microbial testing to verify current processes and practices are achieving those targets, guidelines, or standards, or whether further measures are required.

FSIS is proposing interim targets for pathogen reduction and microbial testing in slaughter establishments. This is an initial step toward measurable reductions in the incidence of contamination of meat and poultry products with pathogenic microorganisms. It also is a first step toward the eventual incorporation of microbial testing as an integral part of process control and verification in facilities operating under the HACCP approach proposed later in this document.

Before describing the proposal for interim targets and microbial testing, a brief description of the Agency's current use of microbial testing is provided.

1. Current Testing Program

FSIS's current regulatory use of microbial testing is generally directed at detecting product that is contaminated with bacteria of particular public health concern.

FSIS has made and will continue to make, on a case-by-case basis, determinations that a meat or poultry product presents an unacceptable public health risk, and is adulterated, due to the presence of specific pathogenic microorganisms in or on the product. Affected product may be processed or raw. The discretionary authority to take immediate action in such cases to protect public health is an essential part of the Agency's food safety mandate.

Processed products that purport to be fully cooked and/or ready-to-eat have been and will continue to be deemed adulterated if found to contain pathogenic bacteria or toxic metabolites. These are products that consumers are likely to eat without further cooking. Consumers should be able to rely on processor's claims, implicit or explicit, that the product is fully cooked and/or ready-to-eat. Such product should in fact be ready to eat; further cooking should not be required to protect the consumer from pathogens.

FSIS currently operates programs to test various products for specified pathogens. Before establishing microbial testing programs, and if there is evidence of a potential public health risk from a pathogen being in or on a particular processed, ready-to-eat product, FSIS performs a risk evaluation that focuses primarily on the pathogenicity of the organism and the seriousness of the resulting disease.

If it is determined that there is a public health threat due to the risk of serious illness from consumption of a contaminated product, the Agency undertakes three related actions. First, product tested and found positive for the prohibited organism or toxin is retained and any implicated product in commerce is recalled voluntarily by the producing establishment. Second, the Agency undertakes a testing program to detect other products similarly contaminated and acquires data to decide if further actions are required. FSIS works with the manufacturer and distributors to return all implicated products to the inspected establishment. Appropriate public notices are given. Recalled product is destroyed or, if appropriate, reprocessed to destroy the contaminant, under FSIS oversight. Third, FSIS works with the establishment to determine the cause(s) of the contamination and to ensure that appropriate processing or other changes are made by the establishment to prevent a recurrence.

FSIS has made numerous determinations in the past that particular pathogens will, if found on a particular processed, fully cooked and/or ready-to-eat product, cause that product to be considered adulterated under the law, and has instituted testing programs accordingly. The following ready-to-eat products are tested for the presence of the microorganisms or their toxins, which, if found, will cause the product to be deemed adulterated, as indicated:

—Cooked beef: *Listeria monocytogenes, Salmonella*
—Sliced ham: *Listeria monocytogenes, Salmonella*
—Cooked meat patties: *E. coli* O157:H7
—Dry and semi-dry fermented sausages: Staphylococcal enterotoxin
—Jerky: *Listeria monocytogenes, Salmonella*
—Large diameter cooked sausages (e.g., bologna, salami): *Listeria monocytogenes, Salmonella*
—Small diameter cooked sausages (e.g., hot dogs, kielbasa, bratwurst): *Listeria monocytogenes, Salmonella*
—Meat and poultry salads and spreads: *Listeria monocytogenes, Salmonella*
—Cooked poultry products: *Listeria monocytogenes, Salmonella*

Most recently, FSIS determined that raw ground beef found to contain *Escherichia coli* O157:H7 is considered adulterated. This determination was made based on several factors. First, only small numbers of the O157:H7 strain of *E. coli* are required to cause serious illness or death, especially among children and the elderly. Second, traditional and accepted cooking practices for raw ground beef (e.g., a medium rare or slightly pink hamburger) do not kill *E. coli* O157:H7. Third, the illness caused by the bacteria can be transmitted to others (especially among highly susceptible small children). FSIS is conducting limited sampling and testing of raw ground beef in establishments and in the marketplace for the presence of *E. coli* O157:H7.

The key characteristic of current FSIS microbial testing programs is that sampling and testing is conducted by FSIS to detect violations and dangerous product contamination and to stimulate preventive measures by industry. Current programs do not involve microbial testing by establishments as part of an effort to verify process control and evaluate the adequacy of an establishment's efforts to control and reduce pathogens. FSIS believes its current testing programs serve a useful purpose but are not adequate by themselves to protect consumers. Microbial testing by companies to verify process control and demonstrate progress toward pathogen reduction is an integral part of FSIS's food safety strategy.

2. Proposed Targets and Testing

One approach to regulating pathogenic microorganisms in meat and poultry slaughter operations would be to determine, based on risk assessments, the levels of specific pathogens on raw meat and poultry products that do not pose a significant risk of illness and

prohibit distribution of products exceeding such levels. The acceptable level of pathogens would be effectively zero (<1 per 25 grams) in at least some cases. The establishment of such standards is the approach generally taken for the regulation of chemical additives in food. It provides a very direct means of controlling and avoiding substances in food that present a public health concern.

FSIS has not taken this approach in the past with respect to pathogenic microorganisms on raw meat and poultry. FSIS has been constrained by the lack of a scientific basis for determining the levels at which specific pathogens do or do not present a safety hazard, particularly in regard to the potential for pathogens to increase or decrease during distribution, marketing and consumption. FSIS also has relied in part on the fact that proper cooking kills pathogens present on raw product. The closest FSIS has come to this approach is its recent decision to treat raw ground beef contaminated with any amount of *E. coli* O157:H7 as adulterated within the meaning of the FMIA, but this was based on the fact that traditional and accepted cooking methods for raw ground beef (such as in a ''medium rare'' hamburger) do not kill this dangerous pathogen.

FSIS believes that determining the levels of specific pathogens that pose a public health risk and using those levels for regulatory purposes is a desirable goal because it provides a very direct means of defining an acceptable level of food safety performance by a meat or poultry establishment and for holding the establishment accountable for achieving it. As a general matter, however, this approach currently is not available to FSIS to deal with the broad array of pathogens in raw meat and poultry. There are large gaps in the scientific knowledge required to determine levels of specific pathogens that do and do not pose a hazard. For example, with certain infectious pathogens where the primary mode of transmission involves cross-contamination, it is currently not possible to correlate pathogen levels with risk of disease (e.g., *Campylobacter jejuni* in raw poultry).

FSIS intends to continue to work with the scientific and public health communities and the meat and poultry industry toward determining what levels of specific pathogens on specific products pose public health concerns requiring regulatory action and to reduce pathogens below those levels to the maximum extent possible. However, the scientific and public health policy issues involved are complex and their resolution will require a concerted, long-term effort. Some of the issues and FSIS's plans for public meetings to begin addressing them are described below in Part III.

For the present, FSIS has decided to pursue an alternative strategy for pathogen reduction that is based on the same principle of articulating an acceptable level of food safety performance and holding establishments accountable for meeting it, but that also takes account of what is achievable today. Specifically, FSIS is proposing interim targets for reducing the incidence of contamination of meat and poultry carcasses and ground meat and poultry products with *Salmonella*, coupled with requirements for all affected establishments to conduct microbial testing to determine whether their targets are being achieved. FSIS believes that significant progress can be made in pathogen reduction by taking advantage of current technologies and industry capabilities, even as the Agency's HACCP program develops and the scientific basis for setting more definitive targets, guidelines or standards evolves.

The proposed *Salmonella* testing program is an important element of FSIS's food safety strategy because it will:

(1) reduce the prevalence of pathogens of public health concern;

(2) induce process changes by some establishments that are needed to achieve both the target for *Salmonella* and a reduction in the frequency and level of contamination of raw meat and poultry with other pathogens;

(3) establish the principle that the FSIS's inspection program and establishment process control programs must begin directly targeting and reducing pathogenic microorganisms of public health concern;

(4) begin building the foundation for HACCP, which will rely on microbial targets, guidelines, and standards to help define the process controls that will be needed to achieve the desired level of food safety performance; and

(5) begin building a database on the prevalence of *Salmonella* contamination, which will be used for national trend analysis and as an essential tool for setting future pathogen reduction goals.

The Agency's interim target and microbial testing proposal includes the following major elements:

(1) selection of *Salmonella* as the target pathogen;

(2) identification of a national baseline occurrence of *Salmonella* contamination for each major species and for ground meat and poultry;

(3) adoption of, as an interim target for pathogen reduction, the requirement that within two years, or some other period specified by FSIS through this rulemaking, each establishment achieve an incidence of contamination below the current mean national baseline;

(4) a requirement that each establishment conduct daily testing for *Salmonella* to determine whether the establishment's process controls are, over a specified period of time, achieving the interim target; and

(5) prompt development and implementation of remedial plans by establishments not meeting the target within a specified period.

The Agency invites public comment on its proposal to establish interim targets for pathogen reduction and require microbial testing. The proposal's major elements are outlined below following a brief discussion of the public health rationale for targeting reduction in incidence of a specific pathogen as a step toward reducing the risk of foodborne illness associated with meat and poultry products.

3. Public Health Benefit of Interim Pathogen Reduction

As noted in earlier portions of this document, *Salmonella, Campylobacter, E. coli* O157:H7, *Listeria monocytogenes, Staphylococcus aureus,* and *Clostridium perfringens* constitute the major bacterial pathogens associated with foodborne illness. *Healthy People 2000* outlines goals for reducing the incidence of each of these pathogens. *Salmonella, Campylobacter, E. coli* O157:H7, and *Clostridium perfringens* appear to be introduced into meat and poultry primarily at the time of slaughter. Public health concerns arise from this initial contamination, in combination with other variables including subsequent handling by industry and the consumer, opportunities for cross-contamination, cooking practices, and the like. These variables have been described in detail in the 1987 National Academy of Sciences report, *Poultry Inspection: The Basis for a Risk Assessment Approach.*

While FSIS cannot quantify the reduction in disease incidence which will occur with specific interim reductions in bacterial contamination of raw product, simply reducing the percentage of product containing a pathogen should result in a reduction in disease incidence, although mishandling may still occur.

Each pathogen has a somewhat different epidemiology, and responds to different interventions in different ways; for example, some interventions may be very effective for *Salmonella,* but have

a minimal effect on *E. coli* O157:H7. For these reasons, it will be important for the long term that testing be pathogen-specific: i.e., establishments should look for what is known to be important in a particular product line, and target interventions and monitoring to that particular pathogenic microorganism. As a part of implementing HACCP, processors will need to determine what pathogens are a major risk for their product, and design interventions and monitoring accordingly.

Even under HACCP, it will not be practical or necessary to test all products for all pathogens. Nonetheless, there are certain pathogens, such as *Salmonella,* which are present on virtually all raw food products. *Salmonella* is the leading cause of bacterial foodborne illness in this country, and causes the greatest economic burden. As such, it is likely that virtually any HACCP based testing program for pathogens on raw product would identify *Salmonella* during the hazard analysis as an organism of primary concern. Based on these considerations, FSIS is proposing reduction in the incidence of product contamination with *Salmonella* as an interim target for pathogen reduction.

FSIS recognizes that reductions in incidence of *Salmonella* contamination does not guarantee equal reduction in other pathogens. Nonetheless, insofar as interventions designed to decrease the incidence of contamination with *Salmonella* reduce overall levels of fecal and ingesta contamination, which is the largest single avenue for contamination of meat and poultry by pathogenic microorganisms, those interventions should have a beneficial effect on other human pathogens of animal intestinal origin. The Agency recognizes that there are other foodborne human pathogens of public health concern that can be isolated from raw meat and poultry product. The Agency would welcome comments on the targeting of other pathogens in addition to or in lieu of *Salmonella.*

The following sections discuss the major elements of the proposed interim targets for pathogen reduction and requirements for microbial testing.

4. Use of Salmonella as a Target Pathogen

FSIS proposes to require that each establishment that conducts slaughter operations or produces raw, ground meat or poultry products sample and test representative product daily for the presence of *Salmonella.*

Due to logistical problems involved with attempting to test for all possible pathogens, the Agency is proposing the use of *Salmonella* at this stage as a target organism. *Salmonella* was selected for this purpose because: (1) intervention strategies aimed at reducing *Salmonella* can be expected to have comparable effects against most other human enteric foodborne pathogens, (2) current methodologies are available to recover *Salmonella* from a variety of products, (3) FSIS baseline data suggest that *Salmonella* colonizes a variety of animals and birds often enough for changes to be detected and monitored, and (4) *Salmonella* is the most common cause of foodborne illness.

5. The Identification of National Baseline Levels as Reference Points for Pathogen Reduction

FSIS proposes that all establishments that conduct slaughter operations or produce raw ground meat or poultry products produce such products such that the frequency of occurrence of *Salmonella* is at or below the current national baseline average. These proposed baseline levels tentatively identified by FSIS are provided in the chart below, showing the frequency of occurrence in terms of the percent of tests expected to be positive for *Salmonella:*

Commodity	Frequency of occurrence of Salmonella (% +)
Steers/Heifers	1
Broilers	25
Raw Ground Beef	4
Fresh Pork Sausages	12
Cows/Bulls	1
Hogs	18
Turkeys	15
Ground Poultry	.....

To the extent possible, FSIS has used data from its Nationwide Microbiological Baseline Data Collection Program as the basis for the proposed baselines assigned to these raw commodities. This program provides data on the prevalence of major pathogens and indicator microorganisms associated with meat and poultry. The data generated from these programs provide a comprehensive microbiological profile of the raw commodities studied. The baseline studies on steers and heifers and ground beef are completed. Studies on cows and bulls, market hogs, and ground turkey and broilers are in progress, while studies are planned for ground chicken and turkeys.

The pathogen reduction baselines for those commodities where FSIS baseline studies have not been completed are estimates based on the best data currently available to the Agency. FSIS recognizes that the data available for some species are limited. The Agency believes, however, that this rulemaking will generate additional data that will help refine the baselines tentatively identified here.

The following is a summary of how the baselines were determined for each of the raw products of concern.

The baseline established for *Salmonella* frequency of occurrence on steer and heifer carcasses is based on the FSIS Nationwide Microbiological Baseline Data Collection study conducted from 1992 to 1993. In this program, 2,089 samples were analyzed for *Salmonella,* as well as other microorganisms, and 1 percent of the samples were found to contain *Salmonella.*

Raw ground beef from federally-inspected establishments was tested by FSIS. Out of 563 samples taken in this baseline study, 4 percent were positive for *Salmonella.*

FSIS has also conducted several, more limited studies which help provide an estimate of the frequency of occurrence of *Salmonella* in regulated commodities, such as broilers, where baseline studies are underway or planned. The data for *Salmonella* on broilers is from a FSIS nationwide study conducted from 1990 to 1992. This survey found *Salmonella* in 25 percent of the 1,874 birds sampled.

A 1979 FSIS study of retail-size, fresh pork sausages showed *Salmonella* in 12 percent of the 603 samples tested. The 12 percent frequency of occurrence for *Salmonella* as a baseline in fresh sausages was derived from this study.

The 1 percent frequency of occurrence of *Salmonella* on cow and bull carcasses is an estimate based on the completed baseline study on steers and heifers. The baseline study for cows and bulls is in progress.

As noted above, FSIS has not completed nationwide surveys for hogs, turkeys, or ground poultry, but such studies are in progress or scheduled for 1995. There have been no studies conducted for *Salmonella* in ground poultry, so revelant data was not available to establish a baseline. Few studies have been conducted for *Salmonella* on hog carcasses. An industry group's recent review of the literature reported several studies of *Salmonella* on pork carcasses conducted between 1961 and 1973. The studies reported wide ranges in the incidence of *Salmonella,* from 49 percent to 56 percent, due in large part to the variety of sampling procedures used. FSIS believes that in the absence of more

recent and comprehensive U.S. data on hogs, the best available data is that provided by a Canadian National Survey, which FSIS believes to be adequate to establish a baseline for *Salmonella* applicable to hogs in the U.S. In the Canadian survey, *salmonellae* were isolated from 17.5 percent of the pork carcasses sampled.

The Canadian study also reported a *Salmonella* frequency of 69.1 percent of the turkey carcasses sampled. However, several U.S. surveys had conflicting results. A study conducted in 1979 showed 6.3 percent of the 79 turkey carcasses sampled were positive for *Salmonella.* Another U.S. survey compared *Salmonella* prevalence in three different establishments. The turkey carcasses positive for *Salmonella* were 13 out of 40 samples (32.5 percent), 6 out of 39 samples (15.4 percent), and 8 out of 40 samples (12.5 percent). Finally, an industry survey conducted from 1987–1988 showed a 15 percent frequency of *Salmonella* on turkey carcasses from the 25 plants that were sampled. The Agency believes these U.S. industry surveys to be the most representative of current conditions and is tentatively proposing to use the figure obtained from the U.S. industry surveys as the proposed baseline for *Salmonella* on turkey carcasses.

The Agency has no data upon which to establish baselines for the other species of food animals subject to mandatory inspection. As such, it is not proposing pathogen reduction target levels for minor livestock species—sheep, lambs, goats, equines—or for minor poultry species—ducks, geese, and guineas—at this time. The minor livestock species together comprise 4–5 percent of all livestock slaughtered, and the minor poultry species comprise only a fraction of 1 percent of domestic birds slaughtered. Assuming that the public risk of foodborne illness from these animals is comparably small, FSIS has decided to focus this rulemaking on the major food species, and defer rulemaking on these minor species. Comment is welcomed on whether FSIS should include these species in its testing program and, if so, on what basis it should do so.

FSIS recognizes that the data currently available to the Agency for determining the current baseline and the appropriate interim target for reduction in *Salmonella* incidence are limited. FSIS is also aware that many meat and poultry companies have been conducting microbial testing, in some cases for many years. The Agency believes that the industry possesses a significant body of data that would help better define the current baseline levels in various products prior to making final decisions on these issues. FSIS strongly encourages the industry and all those who possess relevant data to submit those data to the Agency in response to this proposal and to assist the Agency in adopting appropriate baselines as the reference points for pathogen reduction.

FSIS is also considering and invites comment on alternative approaches to identifying baselines against which pathogen reduction would be measured. One alternative would be to require the use of pathogens other than *Salmonella* as the target organism for certain products. For example, it could be argued that *Campylobacter jejuni/coli* occurs at a greater frequency in poultry than *Salmonella* and as such would be a more pertinent target pathogen. Likewise, according to the available FSIS baseline survey data, beef carcasses have a relatively low incidence of *Salmonella* contamination, suggesting the possibility that other pathogenic microorganisms, such as *Campylobacter jejuni/coli,* might be preferable target organisms for pathogen reduction. FSIS would be prepared to adopt such alternatives if the comments received on this proposal demonstrate that alternative organisms would provide a more effective basis for achieving measurable pathogen reduction in the near term.

Another alternative, discussed further below, would be to use the current performance of a specific establishment as that establishment's baseline for pathogen reduction in lieu of a national baseline.

FSIS also is interested in receiving data showing any correlation between factors other than the species of slaughtered animals and the incidence of pathogenic bacteria. For example, there are suggestions that old animals (e.g., spent hens and culled cows) are more likely than younger animals of the same species to harbor pathogenic bacteria and should be addressed separately.

6. The Interim Targets

FSIS is proposing that each establishment, at a minimum, achieve process control that will bring their incidence of *Salmonella* contamination below the current national baseline incidence of *Salmonella* found on that product within two years of the effective date of this proposed rule.

The baseline levels were chosen as a basis for initial targets in part because they are by definition averages that reflect a distribution of levels among a broad range of establishments. Some establishments have incidences of contamination above the national baseline, while others are achieving rates of contamination below the national baseline. FSIS believes that it is reasonable and feasible to require, as an interim pathogen reduction measure, that all establishments control their processes so that their *Salmonella* incidence is no greater than the current national average.

FSIS is also considering a requirement that, for one or more species, the target for pathogen reduction be some percentage reduction in *Salmonella* below the national baseline, such as a 25 or 50 percent reduction. This option is suggested by statements made by members of industry that many establishments already are achieving a prevalence of contamination well below FSIS's estimated national baseline incidence of *Salmonella* contamination using currently available methods and technologies. In the case of poultry, for example, some companies are reportedly achieving a frequency of occurrence of *Salmonella* contamination as low as 5 percent or less, well below the tentatively identified baseline for broilers and turkeys. The principle underlying FSIS's effort to establish appropriate interim targets for pathogen reduction is that establishments should be moving to adopt process controls and production practices that the industry itself has demonstrated in actual practice are available and effective for reducing the incidence of contamination with pathogenic microorganisms. If reductions 25 or 50 percent below the national baseline are reasonably achievable in the near term for a particular species, all companies should work to achieve them. At the final rule stage, FSIS will adopt specific percentage reductions below the national baseline to the extent they are supported by the administrative record developed in response to this proposal.

FSIS also invites comment on the appropriateness of the proposed two year time period for reaching the interim target following adoption of the final rule. Two years allows ample time for establishments to determine their current performance through the microbial testing FSIS is proposing and implement process controls and interventions that are already available. FSIS may determine on the basis of comments that different time periods, shorter or longer, may be appropriate for one or more species, depending on what is feasible for that species and on the degree of pathogen reduction FSIS adopts as the target. FSIS invites comments on these issues.

7. Requirement for Daily Testing

Each establishment would be expected to collect a minimum of one specimen for testing each day from each slaughter class and/or class of raw ground product, beginning 90 days following publication of the final rule. Once-a-day sampling is based on the natural daily cycle in production processes, starting with daily cleanup. Contamination builds up as operations progress throughout the day. The required sanitation/cleanup returns the level of contamination to essentially zero, thus starting a new cycle. As explained in the next section, FSIS considers one sample a day to be statistically adequate to verify process control.

As alternatives to the one sample per day being proposed in this document, FSIS considered requiring a sampling plan based on establishment production volume, or by lot, which would have meant, for most plants, many more than one sample per species per day. It also considered a sampling plan based on less than one sample per species per day, particularly for small plants. FSIS invites comment on its sampling plan, including the frequency of sampling.

FSIS recognizes that some establishments are currently conducting broader microbial testing than FSIS is proposing, and broader microbial testing will play an important role in an establishment's implementation of HACCP. More than once-a-day testing would have the advantage of providing more rapid analytical verification of process control. However, the Agency is proposing to require only one sample per species per day to achieve the dual purposes of using a statistically valid method and reducing the cost of testing. The Agency believes that maintaining a requirement for species-based testing is needed to provide analytical verification of process control.

As a general matter, single qualitative tests (positive or negative) provide adequate but minimum acceptable information regarding the level of process control. These singular results need to be accumulated over time for process verification. Daily testing (one test per day) was considered to be the minimum sampling required to deliver acceptable sensitivity for detection of process deviations within a realistic timeframe.

FSIS is not proposing at this time to use these testing results for making decisions on the disposition of specific lots of product. The amount of testing FSIS is proposing is not adequate to assure a specific lot is free of *Salmonella*. The purpose of the testing is to verify the performance of an establishment's system of process controls. As explained below, establishments not meeting the target within the specified time will be required to take remedial measures under FSIS inspection.

As proposed, each establishment would develop a written protocol, available for review by Program employees, outlining specimen collection and handling. It would, at a minimum, include:

- Designation of a responsible individual;
- The number of specimens to be collected from each slaughter class and/or species of ground meat and/or poultry;
- Description of random sampling procedure (i.e., how to determine which carcasses are to be sampled to ensure that specimens are representative of that day's production);
- Who will conduct the analysis (e.g., in-house laboratory, commercial laboratory, etc.; and
- Moving sum verification procedure (chart or table).

The designated representative of the establishment would collect the specimen at the end of the production process. For meat this would be prior to the carcass leaving the cooler; for poultry this would be immediately post-chiller; for raw ground meat and poultry, this would be prior to packaging. Samples would be taken as follows:

Poultry: whole bird rinse with the carcass selected after the chiller, at the end of the drip line.

Beef: excised brisket skin tissue, 4 inches (10.2 cm)×4 inches (10.2 cm)×½ inch (1.3 cm) in depth, collected in the cooler, after chilling.

Hogs: excised belly skin tissue, 3 inches (7.6 cm)×5 inches (12.7 cm)×½ inch (1.3 cm) in depth, collected in the cooler, after chilling.

Raw ground meat and poultry products: ½-pound (0.4 kg) sample, collected prior to packaging.

The analytical sample size and the method used would give a result equivalent to the result that would be obtained using the FSIS *Procedure for Isolation and Identification of Salmonella from Food*. (Requests for this document should be sent to the Director, Microbiological Division, FSIS, U.S. Department of Agriculture, Washington, DC 20250.) Samples would be drawn randomly, from all product produced. Samples would be taken for regulatory purposes and, therefore, would be required to meet all of the attributes of an official method (approved for use by Association of Official Analytical Chemists or other recognized scientific body). The method chosen must be verified by in-house data within the testing laboratory.

An establishment would be allowed to test the specimens in its own laboratory or in a commercial/contract laboratory. However, the laboratory that is selected must demonstrate experience in testing meat and poultry for *Salmonella* spp. Either an internal or external laboratory quality assurance/quality control (QA/QC) program with check sample analysis would be required. QA/QC records must be available to FSIS personnel, with FSIS reserving the right to send official samples to the laboratory to verify laboratory capabilities.

The laboratory would record the results and provide the results daily to the establishment, which would enter the results in a chart or table daily to determine whether the process in question is meeting pathogen reduction target levels.

The establishment would provide all the test results at least weekly to Program employees for entry into the FSIS's database. Electronic transmission of test results would be allowed.

8. Determining Compliance With Target Levels

In accordance with the FSIS food safety strategy of articulating what constitutes an acceptable level of food safety performance by a meat or poultry establishment and holding the establishment accountable to that performance, a moving sum statistical procedure is being proposed to evaluate whether establishments are achieving the interim targets for pathogen reduction. The moving sum procedure is a tool for evaluating whether the process control system is functioning and is designed to assess the effectiveness of a system in relation to a specified target level of performance. It focuses on a specific number of days (window) within a production process and evaluates that process to determine whether its performance meets or fails to meet that target level over that period of time.

Using this moving sum procedure, establishments will track the results of end-product testing to evaluate the effectiveness of their production systems for controlling pathogens in relation to the interim target FSIS will be establishing for each specific commodity. This method of evaluation was chosen because it provides an effective means of utilizing the microbiological assessment of end products to verify process control, based on a single sample per slaughter class

and/or class of raw, ground product per day.

FSIS believes the specific approach it is proposing for use of the moving sum procedure will provide an effective means of ensuring that establishments meet the interim targets for pathogen reduction. Any establishment with positive *Salmonella* results at a frequency exceeding that allowed for the product will be readily identified as failing to meet the targets so that remedial measures can be implemented.

As proposed, the microbiological testing laboratory will supply the test results on a daily basis to the establishment. Results would be passed at least weekly to a Program employee for transmission to the headquarters database. Alternatively, the establishment could transmit the data directly to the headquarters database electronically, under the supervision of a Program employee. In addition to being used to verify establishment participation in the program, this information will be used, in addition to baseline data, for national trend analysis.

The establishment would be responsible for entering the results into a moving sum verification table or chart (see sample of moving sum table below). The moving sum is a procedure where results are summed over a predetermined period of time. The moving sum consists of two basic elements, a specified length of time over which results are summed (n) and a maximum number of positives that are allowable within that time frame (AL). These two parameters are based on the target frequency of occurrence of *Salmonella* in that particular commodity and the statistical decision criteria built into the procedure.

An advantage of a moving sum is once the criteria are set, all that is required is a count of the positive results over the most recent window of results.

For example, a chart where the number of days to be summed is 8 (n=8), and the maximum permitted number of positives during that time frame is 3 (AL=3), showing whether the Acceptable Limit is met or exceeded, might look like the following:

Day No.	Test result	Moving sum	Comparison to AL	Days included
1	0	0	Meets	1.
2	0	0	Meets	1, 2.
3	0	0	Meets	1 to 3.
4	1	1	Meets	1 to 4.
5	0	1	Meets	1 to 5.
6	0	1	Meets	1 to 6.
7	1	2	Meets	1 to 7.
8	0	2	Meets	1 to 8.
9	0	2	Meets	2 to 9.
10	0	2	Meets	3 to 10.
11	0	2	Meets	4 to 11.
12	0	1	Meets	5 to 12.
13	0	1	Meets	6 to 13.
14	0	1	Meets	7 to 14.
15	0	0	Meets	8 to 15.

The daily result is recorded as a 1 for a *Salmonella* positive test and a 0 for a negative *Salmonella* test (e.g., the test for day 4 was positive). The value of the moving sum for day 10, for example, is the sum of the daily results for days 3 through 10. This value is merely the number of positives in this window (two). It meets the Acceptable Limit, AL=3.

Several features of moving sum procedures can be noted in the example: (1) There is a startup period (days 1 to 7) in which there are fewer than n=8 results in the sum; (2) a positive affects the moving sum value for n=8 consecutive days; and (3) the moving sum gives equal weight to all days in the window, from the most remote to most current.

FSIS is proposing to specify the moving sum rules for each product class. The chart below specifies the initial time window values (n) and Acceptable Limit (AL) for each product class:

Commodity	Moving sum rules		
	Target (percent positive for *salmonella*)	Window size (n) in days	Acceptable limit (AL)
Steers/Heifers	1	82	1
Cows/Bulls	1	82	1
Raw Ground Beef	4	38	2
Fresh Pork Sausages	12	19	3
Turkeys	15	15	3
Hogs	18	17	4
Broilers	25	16	5

These moving sum rules are based on two assumptions: That the production process is running in-control at the target level specified for the commodity; and that specimens are randomly selected from the end of the production process. They also reflect an effort by FSIS to ensure that an establishment operating consistently within the target will not exceed the Acceptable Limit for positive samples during the window period (and thus trigger remedial action) while providing a high likelihood that establishments regularly failing to meet the target will be detected.

It is important to recognize that this approach to verifying process control in meat and poultry production is designed to assess the effectiveness of a system over time in relation to a specified target level of performance. It is not a means of evaluating and approving individual product lots. The assumptions of an in-control process and randomly selected specimens allow the performance assessment to be separated from production volume considerations.

A number of alternative statistical criteria were considered as the basis for the proposed moving sum procedures, ranging from an 80 to a 99 percent probability of meeting the limit if the process is operating at the target level. The following table shows these alternatives with their corresponding window sizes and Acceptable Limits for *Salmonella* positives. For reasons discussed below, the 80 percent probability was selected.

Probability of passing at target	Target	Window size (in days)	Acceptable limit
80	1	82	1
	4	38	2
	12	19	3
	15	15	3
	18	17	4
	25	16	5
90	1	53	1
	4	28	2
	12	15	3
	15	12	3
	18	14	4
	25	15	5
95	1	36	1
	4	21	2
	12	12	3
	15	10	3
	18	12	4
	25	11	5
99	1	15	1
	4	12	2
	12	8	3
	15	7	3
	18	8	4
	25	9	5

The alternative procedures differ in the probability they give for not exceeding the moving sum limit when a production process is operating at the commodity target. These probabilities range from 80 to 99 percent.

There are at least four considerations involved in selecting a verification procedure: (1) Sampling and testing costs; (2) the nature of the penalties for failing the verification procedure; (3) having a low probability of exceeding verification limits when the producer is meeting the target; and (4) having a high probability of exceeding limits when the producer is not meeting the target. The procedures based on a 99 percent probability of not exceeding the moving sum limit at the target satisfy consideration (3), but do not satisfy consideration (4). Establishment personnel would be very limited in their ability to detect production processes not meeting the target.

There are two ways to improve the ability of the verification procedure to detect when the production process is not meeting the target. One is to increase the number of specimens required to be tested each day, and the other is to lower the probability of passing at the target. In view of the increase in costs to producers that a higher sampling rate would entail and the fact that failing the test does not condemn product (considerations (1) and (2)), FSIS selected the procedures based on an 80 percent probability of passing at the commodity target. The 80 percent probability was selected because it enhanced the chance of detecting marginal performers and provides establishments with an incentive to gear their process controls to achieve frequencies of *Salmonella contamination* well below the proposed interim targets. FSIS retains the discretion to not require remedial measures by establishments that demonstrate they were meeting the interim targets but exceeded the Acceptable Limits by chance.

To further evaluate the moving sum verification procedures, the Agency simulated their performance at percent positive levels greater than the interim target. As an example, the Agency looked at the distribution of the number of days from startup to the first exceedance of the AL for broilers (target of 25 percent) assuming a process percent positive rate of 30 percent. The first exceedance occurred within 22 days in 50 percent of the trials, and it occurred within 70 days in 95 percent of the trials. In other words, a process running at 30 percent positive rate (5 percent above the target of 25 percent) is very likely to be detected within no more than 70 days.

Under the proposed moving sum rules, an establishment operating just at the target would have approximately an 80 percent long-run probability of satisfying (not exceeding) the moving sum limit. Over the long term, the moving sum value will not exceed the AL about 80 percent of the days, assuming that the production process stays on target. The proposed rules also mean that an establishment operating just at the target has a 20 percent chance of exceeding the Acceptable Limit and triggering remedial action. This is consistent with the Agency's objective in establishing interim targets as a first step toward holding establishments accountable for meeting acceptable levels of food safety performance, because, due to the variability in pathogen levels, establishments consistently operating at or just below the target are likely to exceed the target from time to time.

The selection of 80 percent as the criterion for establishing the proposed moving sum rules is intended to provide establishments with an incentive to design their process controls in a manner that will achieve pathogen reduction significantly below the designated interim target. As in any random sampling scheme, there is a chance of actually having positive results, even if the process is meeting the criteria. However, an establishment can decrease its probability of exceeding the AL (by chance alone) by targeting its process to produce product with a lower frequency of positive samples. For instance, the establishment could gear its process controls toward a 20 percent target as opposed to the 25 percent target specified for broilers. This would benefit the establishment by providing a greater assurance of not exceeding the AL, since its own target is lower than the designated one.

A document giving a more detailed explanation of the moving sum verification procedure will be made available by FSIS to those wishing more information on this aspect of the proposal. Requests should be sent to Assistant Deputy Administrator for Science, FSIS, U.S. Department of Agriculture, Washington, DC 20250. FSIS welcomes comments on alternative ways by which the Agency and establishments may ascertain how well process controls are achieving national target levels.

9. Establishment Action Required for Exceeding Target Limits

The establishment will have 90 days from the effective date of the rule to establish microbiological testing regimes. Six months from promulgation of the regulations establishments will be required to track these interim target results using a moving sum verification procedure and report the results to FSIS. Two years after promulgation of the rules, establishments that are not achieving the interim targets for pathogen reduction will be required to take corrective action under FSIS supervision. In such instances, a review by the establishment of its production practices and process controls is required. A written report of the evaluation, including any identified process failures and proposed corrective actions, would be submitted to the

Inspector in Charge within 14 days from the day the process exceeded the limits. This report would have to be updated on a weekly basis until the process is back within the Acceptable Limit.

During the time the results exceed the moving sum limit, sampling should be conducted at a higher rate of at least two specimens per day. This will provide more accurate and timely data for effective decisionmaking. This increased sampling has the advantage that, assuming that the problem causing the initial deviation from the target limit has been identified and corrected, the extra samples per day will shorten the time frame (window) during which the establishment would be considered operating above targets. The sampling rate would return to normal when the moving sum value meets the AL. Additional testing may be conducted by FSIS, at the Agency's discretion, as necessary to assist firms in meeting pathogen reduction targets.

10. Relationship to HACCP

Once an operation has a history of consistent control and is operating within the established limits, improvements in technology and increased understanding of process control can be used to further enhance pathogen reduction efforts. The continuous review of the production process with corresponding improvements should set the stage for implementation of state-of the-art process controls, namely HACCP.

FSIS is aware of and continues to encourage establishments to implement effective HACCP programs as soon as possible. Establishments that can demonstrate that their HACCP process controls produce only products that meet or exceed the proposed targets for pathogen reduction, and have an alternate verification program may, upon approval by the Administrator, continue their current operating procedure in lieu of the proposed verification program.

All establishments that have slaughter operations or produce raw, ground beef or poultry are required to participate in this program unless prior approval is granted by the Administrator, in a situation where an establishment has instituted a HACCP system. That system includes pathogen testing which, in the judgment of the Administrator, meets or exceeds the testing requirements in the proposed regulations.

11. Alternative Approaches to Establishing Pathogen Reduction Baselines and Targets

The principle underlying the proposed approach to pathogen reduction outlined above is that production of raw meat and poultry with an incidence of *Salmonella* at or below the national incidence level is readily achievable with available technology and production methods and that all establishments should be required in the relative near term to perform at this level. This would establish a national standard for food safety performance on which future pathogen reduction efforts could be built. One potential disadvantage of this approach is that it does not take account of the likelihood that current incidence levels of *Salmonella* contamination vary widely. In the case of broilers, for example, FSIS believes that some establishments are already performing well below the 25 percent baseline incidence found in the FSIS survey—at a 5 percent incidence level or lower—while many establishments are performing well above that level. Some of the poorer performing establishments may not be able to achieve reductions to the targeted prevalence of contamination in the near-term. The better performing companies—ones already performing well below the national baseline—may feel economic pressure to relax their pathogen reduction efforts to compete under a standard that is less strict than they are already achieving.

An alternative approach would be to establish the initial baseline for pathogen reduction on an establishment-specific basis and to require significant interim reductions in each establishment from its baseline. Such baselines would be established on the basis of either reliable existing data from that establishment or on a brief required period of sampling and testing in each establishment for the target pathogen.

This approach would have some advantages. It would take account of the likelihood that current performance in terms of incidence of *Salmonella* contamination varies widely. Requiring, for example, a 50 percent reduction from the establishment-specific baseline would ensure that some pathogen reduction is achieved by all establishments and a larger reduction, in absolute terms, would be required by establishments that currently have higher incidences of contamination. This approach might achieve a greater overall reduction in incidence of contamination, depending on the percent reduction required for each establishment and the actual current distribution of incidence rates across all establishments.

The establishment-specific baseline approach has disadvantages. It would be more difficult to administer because it would require the creation of approximately 2,500 establishment-specific baselines, and it would not be based on the principle that there should be a nationally recognized measure of food safety performance, regardless of the establishment in which a product is produced. The establishment-specific approach would also fail to recognize that some establishments are already operating in accordance with the current state of the art and may have difficulty achieving significant additional reduction in the near term.

The latter concern might be addressed by hybrids of the two basic alternatives outlined above. For example, establishments currently above the national baseline could be required to reduce the incidence of contamination to some level at or below the national baseline, while the better performing establishments could be required to maintain their current level of performance, perhaps within some appropriate range.

FSIS invites public comment on these and other possible alternatives to its proposed approach. At the final rule stage FSIS intends to adopt an approach to setting interim targets for pathogen reduction that takes into account its proposal, the alternatives outlined here, and the comments received during the course of this rulemaking.

C. Hazard Analysis and Critical Control Point (HACCP) Systems

1. Background

Overview of Rationale for Adopting HACCP

After having introduced key HACCP concepts and controls into federally inspected establishments through the proposed near-term interventions and microbial testing program discussed earlier in this document, FSIS would secure its long-term strategy for improving the safety of meat and poultry products by requiring that all such establishments adopt HACCP systems. HACCP is a systematic approach to the identification and control of hazards associated with food production that is widely recognized by scientific authorities, such as the NAS and the NACMCF and international organizations, such as the Codex Alimentarius Commission, and the International Commission on Microbiological Specifications for Foods (ICMSF), and used in the food industry to produce product in compliance with health and safety requirements. HACCP provides assurances and documentation that processes used in manufacturing meat and poultry products are in control

and producing safe, wholesome, unadulterated products.

FSIS is proposing these regulations because a system of preventive controls with documentation and verification of successful operation is the most effective approach available for producing safe food. Emphasis by the regulated industry on improving the control of microbiological hazards in raw and cooked products in conjunction with process control will reduce the risk of disease resulting from the presence of pathogenic microorganisms in meat and poultry products.

HACCP is a conceptually simple system by which meat and poultry establishments can identify and evaluate the hazards that could affect the safety of their products, institute controls necessary to keep these hazards from occurring, monitor the performance of these controls, and maintain records of this monitoring as a matter of routine. The HACCP systems mandated in these proposed regulations will be limited to attributes affecting product safety, as opposed to economic adulteration and quality parameters. If these regulations are adopted, FSIS will verify HACCP system operations as part of its program of continuous inspection.

FSIS is proposing to make HACCP mandatory for the meat and poultry industry for the following reasons:

(1) Adoption of HACCP controls by the meat and poultry industry, coupled with FSIS inspection activities designed to verify the successful operation of the HACCP system, will produce a more effective and more efficient system for ensuring the safety of meat and poultry products than currently exists. HACCP appropriately places responsibility on meat and poultry establishments to demonstrate an understanding of hazards and risks associated with their products and an ability to control the processes they use.

(2) A federally mandated HACCP system will provide the basis for a modernized process control system capable of dealing with all the hazards that might be associated with meat and poultry products currently and in the future—biological, physical, and chemical.

(3) The expertise for applying HACCP to meat and poultry processes and products is in an advanced state of development. Considerable progress in applying HACCP to meat and poultry processes has already been achieved by FSIS and other USDA agencies (e.g., the Extension Service). Work has also been done by other Federal agencies, several States, by academic institutions, by industry trade associations and independent industry members.

(4) HACCP has a broad base of support. In March 1994, a variety of constituent interest groups including consumers, the regulated industry, scientists and other professionals, producers, employee representatives, and other Federal and State governmental representatives endorsed the HACCP approach as embodied in the seven principles set forth by the NACMCF.

Meat and poultry industry representatives have urged the Federal government to institute the mandatory use of a HACCP-based production system for their products. In a recent letter, the American Meat Institute (AMI) has petitioned the Agency to begin rulemaking to mandate HACCP.

Members of the International Meat and Poultry HACCP Alliance strongly support implementation of a mandatory HACCP program. The Alliance consists of approximately 30 industry associations, 10 professional associations, 32 university affiliates, 6 service groups, 6 Government representatives and 5 foreign government representatives.

In its 1993 report, *Creating a Government That Works Better and Costs Less,* Vice President Gore's National Performance Review recommended that: ''[USDA] require all food processing establishments to identify the danger points in their processes on which safety inspections would focus * * * also [to] develop rigorous, scientifically based systems for conducting inspections. * * *''

(5) A federally mandated HACCP system of preventive process controls appears to be a prerequisite to continued access to world markets. For example, the United States' largest trading partner, Canada, has announced its intention to implement HACCP for meat and poultry processes by 1996. Australia and New Zealand are also implementing HACCP-based programs.

(6) Use of the limited public resources available to assure the wholesomeness of the meat and poultry supply can be significantly more effective if all meat and poultry establishments are controlling their processes through HACCP systems. HACCP systems focus attention on hazards to product safety and steps critical for their effective control. HACCP systems generate data that can be used to continuously assess whether the process is in control, and, when deviations occur, what was done to correct the problem. These two characteristics of HACCP systems will mean that inspector attention can be directed to the safety related elements of the process and that inspector review can utilize objective measures of how well the controls have been working.

(7) Implementation of mandatory HACCP systems in inspected establishments permits separation and clarification of the differing roles of establishment and inspection personnel. HACCP is an industry process control system. Holding the industry responsible for the development and effective operation of HACCP systems makes it clear that production of wholesome meat and poultry products is industry's responsibility, not the responsibility of the inspection service. The role of the regulatory agency under HACCP is verification that the establishment is controlling its processes and consistently producing complying products.

Since all raw meat and poultry products contain microorganisms that may include pathogens, raw food and the products made from it unavoidably entail some risk of pathogen exposure and foodborne illness to consumers. However, since pathogens are not visible to the naked eye, consumers have no way to determine whether the food they buy is safe to handle and eat. When foodborne illness does occur, consumers often cannot relate the symptoms they experience to a specific food—or any food—because symptoms may appear after some time has passed. Thus, food safety attributes are often not apparent to consumers either before purchase or immediately after consumption of the food. This information deficit also applies to wholesalers and retailers who generally use the same sensory tests—sight and smell—to determine whether a food is safe to sell or serve.

The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by preventable pathogenic microorganisms. When consumers cannot trace an illness to any particular food or even be certain it was caused by food, food retailers and restaurateurs are not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors may have little incentive to incur costs for more than minimal pathogen and other hazard controls. The Agency believes that today about as much process control exists as current market incentives are likely to generate. The existence of significant foodborne illness demonstrates the inadequacy of the status quo. Thus, if foodborne illness is to be reduced, there must be

an increase in systematic process control throughout the industry. FSIS believes this need is best satisfied by a mandated HACCP program.

The Agency invites comment on its rationale for mandating HACCP rather than relying on market incentives to induce voluntary adoption of HACCP. FSIS also invites comment on whether market incentives can be increased or harnessed to improve food safety as a supplement or alternative to the measures proposed in this rulemaking. FSIS invites comment specifically on the role label claims about the safety or safety-related processing of meat and poultry products might play in encouraging and responding to market demand for safer food products.

The Principal Hazards Addressed by HACCP

Meat and poultry products may present physical, chemical or biological (including microbiological) hazards to consumers.

Physical hazards may include extraneous materials of various kinds that could be introduced into product during slaughtering and processing operations. Usually, these extraneous materials (e.g., ''buckshot''; barbed wire, glass or metal pieces) are easily prevented from getting into the product at all and can be detected while the product is still in the inspected establishment. Other physical hazards result directly from slaughtering and processing operations (e.g., bone chips and feathers). Random product examinations and finished product standards are presently used to control these hazards.

Chemical hazards might result from residue contamination, improper formulations, or use of compounds not intended for food purposes. The results from the past several years of FSIS's residue-monitoring program suggest that contamination of the meat and poultry supply with violative levels of chemical residues is relatively rare; although FSIS test results cannot be extrapolated conclusively to all chemicals in all products, 0.29 percent of analyses detected violative residues in 1993. Chemical contamination from improper formulations and inadvertent or incorrect use of non-food compounds is usually prevented by in-plant control activities.

The issue of responsibility for primary control of hazards presented by chemical residues was raised by GAO in its recent report, ''Food Safety: USDA's Role Under the National Residue Program Should be Re-evaluated'' (RCED–94–158). GAO reported that while Federal resources for residue control cannot keep pace with the industry's growth, the industry has recognized that it must ensure, and document that its products comply with applicable residue standards.

* * * the Congress may wish to consider[:]

—Requiring FSIS to establish scientific, risk-based HACCP systems with the industry for residue prevention, detection and control;

—Having FSIS shift primary responsibility for day-to-day residue prevention, detection and control to the industry; and

—Requiring FSIS to adopt a regulatory oversight role designed to ensure the effectiveness of the industry's efforts.

FSIS accepts and agrees with the direction of these recommendations and believes that mandatory HACCP for slaughter and processing operations presents the opportunity to make this shift so that the industry is more completely responsible for the safety of its products with respect to the chemical hazards presented by residues, especially animal drugs.

Biological hazards associated with disease conditions in animals are presently addressed by specific FSIS disease inspection techniques. Hazards include such disease conditions as anthrax, tuberculosis, brucellosis, leukosis, cysticercosis, and other septicemic and toxemic conditions. The detection and control of these hazards is accomplished through ante- and postmortem inspection performed by FSIS employees on livestock and poultry. When, upon examination, livestock and poultry display signs or symptoms of disease, they are condemned or subject to restrictions, such as ''passed for cooking only.'' Parasitic conditions are also the subject of inspection procedures.

Several human pathogens of enteric origin do not normally produce signs or symptoms of disease in animals or birds but will produce foodborne illness in humans. These microorganisms are among the most significant contributors to foodborne illness associated with consumption of meat and poultry products, but present inspection techniques are not effective in detecting and controlling the presence of pathogens on raw products.

Processing procedures used to manufacture ready-to-eat products are designed to destroy pathogenic microorganisms and, if properly conducted, are effective. Microbiological testing is used to verify these processing procedures. In 1993, there were 11 voluntary recalls involving 1.7 million pounds of product for bacterial contamination in ready-to-eat products. These recalls were principally the result of detecting *Listeria monocytogenes*, which is frequently a post-processing environmental contaminant, and not an indication of a failure of the heat treatment procedure to produce a pathogen-free product.

As explained in earlier sections of this document, there is a compelling public health need to establish systematic process controls for raw meat and poultry products, to prevent their contamination by pathogenic microorganisms and to reduce contamination when it unavoidably occurs. These proposed rules will, for the first time, mandate adoption of a system of control for all federally inspected meat and poultry establishments, build on the foundation of the food safety initiatives proposed earlier in this document, provide FSIS an effective means to verify that establishments are meeting their food safety responsibility with respect to pathogenic microorganisms, and provide the basis for the science-based inspection system of the future.

Overview of HACCP Principles

The HACCP approach to food safety was first developed by the Pillsbury Company as a means of assuring the safety of foods produced for the U.S. space program. The National Aeronautics and Space Administration (NASA) wanted a ''zero defects'' program to guarantee safety in the foods astronauts would be consuming in space. When NASA and Pillsbury critically evaluated available systems for ensuring food safety, they found that, even when very large numbers of finished product samples were tested, a relatively large percentage of potentially hazardous product could still be accepted. Pillsbury then introduced and adopted HACCP as a system that could provide the greatest assurance of safety while reducing the dependence on finished product sampling and testing. HACCP, by virtue of identifying the hazards inherent in the product and process, and devising preventive measures that could be monitored, would control the process. Pillsbury recognized that HACCP offered real-time control of the process as far upstream as possible by utilizing operator controls and continuous monitoring. Through this approach, Pillsbury dramatically reduced the risk of microbiological, chemical, and physical hazards by anticipation and prevention rather than inspection.

The presentation of the HACCP system by the Pillsbury Company at the 1971 U.S. National Conference on Food Protection led to gradual recognition of the value of the HACCP approach. This

was reflected in the incorporation of the HACCP principles into FDA's regulations for low-acid canned foods in 1973 to address serious botulism problems in the canning industry. During the intervening years, the concepts and rationale for utilizing the HACCP approach have slowly gained acceptance throughout the food industry and scientific community.

The USDA and the Department of Health and Human Services (HHS) established the NACMCF in 1988 at the recommendation of the NAS to advise the two departments on food safety issues. In 1992, the NACMCF endorsed HACCP as an effective and rational means of assuring food safety from harvest to consumption.

The Committee formulated seven principles to be employed in the development of HACCP plans. These principles include hazard assessment, critical control point identification, establishing critical limits, monitoring procedures, corrective actions, recordkeeping, and verification procedures. Under such a system, if a deviation occurs indicating that control has been lost, appropriate steps are taken to reestablish control in a timely manner to assure that potentially hazardous product does not reach the consumer. A complete description of the seven HACCP principles recommended by the NACMCF can be found in the Committee's March 20, 1992, publication, ''Hazard Analysis and Critical Control Point System.'' As outlined in a later section, FSIS has adopted the seven HACCP principles as articulated by the NACMCF, and is proposing that all HACCP plans include the principles. A discussion of the seven HACCP principles and associated HACCP plan elements follows:

Principle No. 1: Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur, and describe the preventive measures.

The first step in establishing a HACCP system for a food production process is the identification of the hazards associated with the product. NACMCF defined a hazard as any biological, chemical, or physical property that may cause a food to be unsafe for consumption. For inclusion in the list, the hazard must be of such a nature that its prevention, elimination, or reduction to acceptable levels is essential to the production of a safe food. Hazards that involve low risk and severity and that are not likely to occur need not be considered for purposes of HACCP. Examples of several questions to be considered in a hazard analysis include: (1) Does the food contain any sensitive ingredients? (2) Does the food permit survival or multiplication of pathogens or toxin formation during processing? (3) Does the process include a controllable processing step that destroys pathogens? (4) Is it likely that the food will contain pathogens and are they likely to increase during the normal time and conditions under which the food is stored prior to consumption? (5) What product safety devices are used to enhance consumer safety (e.g., metal detectors, filters, thermometers, etc.)? (6) Does the method of packaging affect the multiplication of pathogenic microorganisms and/or the formation of toxins? and (7) Is the product epidemiologically linked to a foodborne disease?

Principle No. 2: Identify the CCP's in the process.

A critical control point (CCP) is defined as a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. All significant hazards identified during the hazard analysis must be addressed.

The information developed during the hazard analysis should enable the establishment to identify which steps in their processes are CCP's. To facilitate this process, the NACMCF developed a CCP decision tree which can be applied to an identified hazard at each step of the process (see Figure 3, below). The decision tree asks a series of ''yes'' or ''no'' questions to assist in determining whether a particular step is a CCP.

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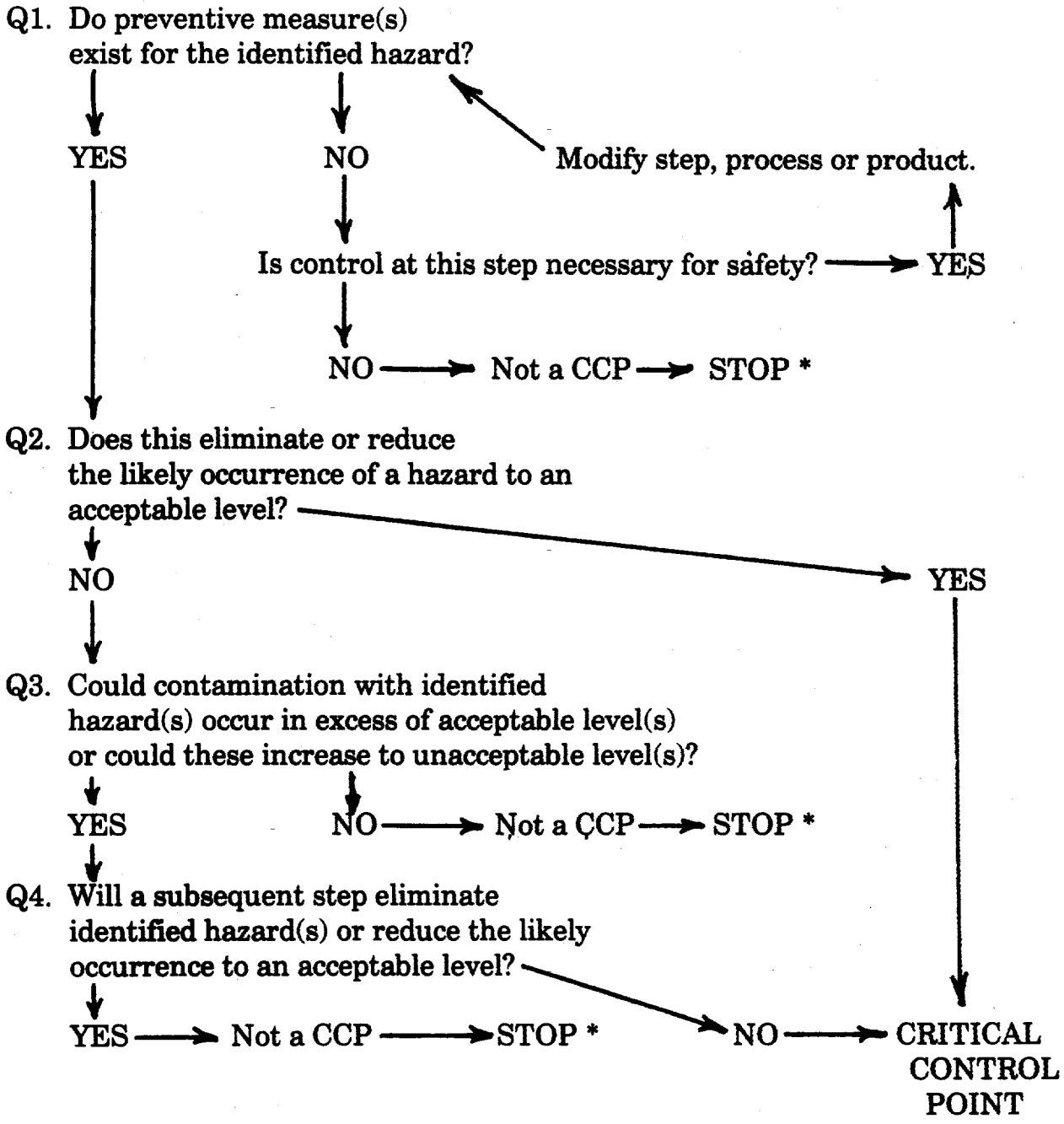
Figure 3. CCP Decision Tree (Apply at each step of process with an identified hazard.)



* Proceed to next step in the described process.

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Examples of CCP's may include, but are not limited to: cooking, chilling, specific sanitation procedures, product formulation controls, prevention of cross contamination, and certain aspects of employee and environmental hygiene. All CCP's must be carefully developed and documented.

Consistent with the principles of the NACMCF, FSIS is proposing to require that establishments identify CCP's for food safety hazards in their HACCP plans. All three types of hazards (physical, chemical and biological, including microbiological) must be addressed and controlled.

FSIS believes that implementation of mandatory HACCP, in conjunction with related changes described elsewhere in this document, will result in less risk of foodborne illness being associated with these products. Therefore, identification of CCP's throughout the production process for controlling microbial hazards is particularly important.

Principle No. 3: Establish critical limits for preventive measures associated with each identified CCP.

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Another way of considering critical limits is that they serve as boundaries of safety for each CCP.

Critical limits are most often based on process parameters, such as temperature, time, physical dimensions, humidity, moisture level, water activity, pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory information, such as texture, aroma, or visual appearance in relation to the growth or survival of target pathogens or chemical or physical hazards. Establishment of critical limits should be justifiable in relation to knowledge available from such sources as the meat and poultry regulations or guidelines, literature, surveys, experimental studies, or from recognized experts in the industry, academia, or trade associations.

In accordance with the principles set forth by NACMCF, FSIS is proposing that processors identify critical limits in their HACCP plans that must be met at each CCP to be certain that the hazard is controlled. Critical limits must reflect relevant FSIS regulations, FDA tolerances, and action levels where appropriate. Processing establishments are encouraged to establish critical limits more stringent than those now in FSIS regulations or related documents to ensure that regulatory requirements are routinely met even when deviations occur. If critical limits more stringent than regulatory limits or requirements are set, then the establishment must meet those more stringent limits.

Principle No. 4: Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

Monitoring is observations or measurements taken to assess whether a CCP is under control. Monitoring is used to determine when a deviation occurs at a CCP; therefore, monitoring procedures must be effective. There are many ways to monitor CCP critical limits on a continuous or batch basis; however, continuous monitoring is always preferred. When continuous monitoring is not feasible, frequencies must be sufficient to ensure that the CCP is under control. Statistically designed data collection or sampling plans need to be developed in such instances.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Personnel assigned the monitoring activities must be properly trained to report all results, including any unusual occurrences, so that adjustments can be made and any processes or products that do not meet critical limits are identified so that immediate corrective actions may be taken.

Monitoring activities are necessary to assure that the process is in fact under control at each critical control point. Some monitoring procedures could be accomplished by automatic instruments and devices such as time/temperature recording devices. Some monitoring procedures could consist of checks performed, with outcomes recorded. Other monitoring procedures might involve rapid testing technologies that provide feedback within appropriate time frames, for example, the use of quick tests to verify levels of chlorine in poultry chillers.

HACCP requires establishments to systematically monitor, control, and, where necessary, adjust their production processes to meet a specified standard. Process monitoring may necessitate materials or devices to measure, test, or otherwise evaluate the process at critical control points. Examples would be such items as thermometers and test kits.

FSIS is proposing to require that procedures for monitoring each CCP be identified in the HACCP plan. These monitoring procedures should assure that the monitoring systems are capable of detecting process deviations, including product segregation and holding procedures, effect of deviations on product safety, indicators for modification of the HACCP plan, and the establishment employee responsible for monitoring activities.

Principle No. 5: Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.

A HACCP system is designed to identify potential health hazards and to establish strategies to prevent their occurrence. However, ideal circumstances will not always prevail in a processing operation and deviations will occur. In such instances, the NACMCF points out that corrective action plans must be in place to: (1) determine the disposition of the non-compliant product and (2) identify and correct the cause of the deviation to regain control of the CCP. Individuals who have a thorough understanding of the process, product, and HACCP plan should be identified and assigned responsibility for making decisions. When appropriate, scientific experts must be consulted to determine disposition of the product.

FSIS is proposing to require that establishments describe in their HACCP plans the corrective actions that will be taken if a critical limit is not met. Corrective actions must be specified in sufficient detail to ensure that no public health hazard exists after these actions have been taken. Although the process of developing a HACCP plan emphasizes organized and preventive thinking about what is occurring as the meat or poultry product is being manufactured, the existence of a HACCP plan does not guarantee that problems will not arise. For this reason, the identification of a planned set of activities to address deviations is an important part of a HACCP plan.

Principle No. 6: Establish effective recordkeeping procedures that document the HACCP system.

The NACMCF points out that an establishment's HACCP plan and all associated records must be maintained on file at the establishment, and provides several examples of records that could be maintained, such as those relating to incoming ingredients, product safety, processing, packaging, storage, and distribution, deviations and corrective actions, and employee training.

A HACCP system will not work unless records are generated during the operation of the plan, and those records are maintained and available for review. One of the principal benefits of a HACCP process control system to both industry and regulatory officials is the availability of objective, relevant data. Thus, FSIS is proposing to require that the HACCP plan provide for a recordkeeping system that will

document the establishment's CCP monitoring, verification activities, and deviation records. FSIS has also concluded that recordkeeping systems are much more effective when they include the actual values obtained, as opposed to terms such as ''satisfactory'' or ''unsatisfactory,'' which reflect a judgment about the values and do not permit trend analysis.

Principle No. 7: Establish procedures to verify that the HACCP system is working correctly.

The NACMCF defines verification as the use of methods, procedures, or tests in addition to those used for monitoring, to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation. Four processes are identified as steps in the establishment's verification of its HACCP system.

The first process is the scientific and technical process to verify that all critical limits at CCP's are adequate and sufficient to control hazards that are likely to occur in their specific process(es). This is commonly referred to as ''validating'' the process.

The second process is to ensure that the HACCP plan functions properly. Establishments should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, review of CCP records, and determinations that appropriate management decisions and product dispositions are made when deviations occur.

The third process consists of documented periodic reviews to ensure the accuracy of the HACCP plan. Such reviews should include an on-site review and verification of all flow diagrams, CCPs, critical limits, monitoring procedures, corrective actions, and records maintained.

The fourth and final verification process deals with the regulatory agency's responsibility and actions to ensure that the establishment's HACCP system is functioning satisfactorily. This verification can be viewed as an overall process validation and can consist of any and all of the verification activities mentioned above, plus final product testing to demonstrate compliance with regulatory as well as other desired performance standards.

FSIS is proposing to require that the HACCP plan include a set of verification tasks to be performed by establishment personnel. Verification tasks will also be performed by FSIS personnel. However, an important benefit of HACCP is for establishments to take full responsibility for producing a safe product. Thus, it is envisioned that establishments, as well as the regulatory agency, will undertake final product testing as one of several verification activities. Verification tasks provide an opportunity to demonstrate that a well-functioning HACCP system is in fact controlling a process so that safe product is being produced under conditions that minimize preventable risks.

The verification principle also links HACCP with the key element of the FSIS regulatory strategy for pathogenic microorganisms, which is the establishment of public health-oriented targets, guidelines, or standards establishments must meet to engage in commerce. Without some objective measure of what constitutes an acceptable level of food safety performance with respect to pathogenic microorganisms, it would be impossible to determine whether an establishment's HACCP plan is acceptable and functioning effectively. FSIS is taking the first step toward implementation of such objective measures with the proposed interim targets for pathogen reduction, which focus on *Salmonella.* As data become available, these targets will be refined, and possibly expanded in slaughter operations and extended in processing operations, to support the Agency's implementation of HACCP. Verification might well include required microbial testing for all processes and species. Eventually, such testing can be expected to be an integral part of HACCP verification.

FSIS Experience With HACCP

(1) FSIS HACCP Study, 1990–1992.

In 1990, FSIS initiated a study of HACCP that focused on how this system of process control could be applied within the meat and poultry industries and what the implications might be for regulatory inspection activities. This study was not designed to establish the efficacy or benefit of the HACCP approach as a process control system. Recognition of HACCP as a proven method for preventing and controlling food safety hazards has been achieved through practical application of the concepts to food production operations since 1971.

Recognizing that acceptance of HACCP within the meat and poultry industries would be dependent on a broad range of constituent support, the FSIS study involved consultations and public hearings; technical workshops with representatives of industry, academia, and trade associations to develop generic HACCP models; and testing and evaluation of in-plant trials through case studies. In-plant testing involved operational application of generic models for refrigerated foods, cooked sausage, and poultry slaughter in nine volunteer establishments.

The study underscored the significance of the change in roles and responsibilities that use of a HACCP system brings both to the regulated industry and to the inspection service. This finding would later be supported by observations at a Round Table meeting on HACCP in 1994 that successful HACCP implementation will demand a culture change within the inspection service and within the industry. Additionally, the Agency's earlier experiences with HACCP-based regulations, such as those for low-acid canned foods, cooked roast beef, and, more recently, for cooked, uncured patties had demonstrated the advisability of technical collaboration. The study experience confirmed these earlier conclusions that technical collaboration was essential to successful implementation of HACCP.

(2) HACCP Round Table, 1994.

FSIS was proceeding during 1993 to develop a HACCP regulation when a group of concerned constituent organizations requested greater pre-proposal involvement and public consultations prior to publication of proposed regulations. USDA agreed to have a public event at which the application of HACCP in the meat and poultry industry could be discussed. This event became known as the HACCP Round Table.

On March 30 and March 31, 1994, FSIS held a two-day Round Table meeting in Washington, D.C. Participants in the Round Table were primarily selected by a procedure announced in the **Federal Register** on January 13, 1994. Participants included public health officials, representatives from the meat and poultry industry, consumer groups, scientists and professional scientific organizations, producer and farmer groups, USDA and other Federal, State, and local employees. Prior to the Round Table, a steering committee of nine of the Round Table participants determined the key issues to be addressed during the forum. For each key issue, a particular question was developed to focus the deliberations. Each issue, question, and deliberation is summarized below. FSIS's views on those issues addressed by this regulation are covered under ''Discussion of HACCP Proposal'' below. A report on the HACCP Round Table has been published and is available from the FSIS Docket Clerk at the address provided under **ADDRESSES**.

HACCP Plan Approval: What is the best way to ensure that HACCP plans effectively incorporate the seven HACCP principles?

There was broad support for incorporating the seven HACCP principles into HACCP plans. Different perspectives were expressed concerning the means by which this might be achieved. These perspectives ranged from having plans developed by certified experts, to the use of objective baseline data from industry operations, and to the use of generic models. Having and applying generic models and guidelines to plant specific situations was considered desirable.

Training/Certification: What should be the role of FSIS with regard to industry HACCP training?

This question generated discussion on three components: (1) HACCP curricula, (2) training approaches, and (3) certification requirements. The centrality of training to successful implementation of HACCP is reflected in the broad range of perspectives offered. Curricula concerns ranged from the need for uniform training on principles, to the need for specific training on application of the principles within a particular establishment operation, to the need for joint training between inspectors and industry employees. Training approaches touched on the need for training to be both available and affordable, and the potential for training development and delivery to occur within various private sector organizations as well as academia. Certification requirements addressed the alternatives of having HACCP-trained personnel in establishments, having HACCP consultants available on-call, and having some type of certification process for such individuals.

Phase-in: Should the mandatory HACCP requirement be phased-in and, if so, how?

There was broad support for the notion of phasing-in HACCP requirements, since allowing enough time for the HACCP program to develop and grow is deemed critical for its success. Proceeding on a deliberate schedule allows for an orderly transition within the industry and permits adjustments of the regulatory infrastructure to suit the HACCP structure within inspected establishments. A variety of approaches to phase-in and timing were offered. A second point raised was that the phase-in should take advantage of existing HACCP knowledge and expertise, advancing first those industry segments whose process control operations are more closely aligned with HACCP. A third point offered was that the phase-in should provide for a transition or trial period as application of HACCP occurs within a particular establishment.

Measures of Effectiveness: How can it be determined initially, and on a continuing basis, that HACCP plans are working effectively?

Participants discussed the need to develop measures of effectiveness for HACCP plans. These ranged from the use of baseline data on the process, establishment, and product level; to the use of microbial, physical, and chemical guidelines; to the use of in-process, as well as end-product testing; to the openness and accessibility of data and records on selected measures of effectiveness. There was considerable discussion concerning the need for finished product testing to support verification of a HACCP program. The area of greatest controversy was the need for microbial testing and the development of microbial guidelines in conjunction with the need for finished product testing. Different perspectives were offered on these issues, on how such testing could be accomplished, and on the practical limits of detection, sample collection, and testing.

Compliance/Enforcement: What are the best ways to adequately enforce and ensure compliance with HACCP requirements?

Participants presented views on the types of regulatory authority that would be appropriate in a mandatory HACCP system. Viewpoints ranged from those who believed that current enforcement authorities are adequate, to those who stated a need for new authorities (e.g., civil penalties) and those who believed a review of enforcement authorities should be undertaken to reflect the changes in roles and responsibilities between the industry and the inspection service. There was significant discussion concerning deviations from HACCP requirements and how these deviations should be handled, including appropriate enforcement responses to repeated deviations from the HACCP plan. Here, two major points of view were articulated. The first view was that any deviation from a HACCP plan could result in a regulatory remedy (rather than criminal remedy) and that a deviation from a CCP, while a food safety concern, should result in a regulatory response related to the level of severity (in terms of risk to human health) of the deviation. The second view was that any deviation from the HACCP plan constitutes adulteration, hence a violation of law subject to enforcement action. This view holds that, since HACCP is intended to address potentially serious food safety hazards, a deviation is a violation. A final point of discussion on this issue was employee protection from reprisals for reporting food safety hazards (e.g., whistleblower protection for industry employees).

Relationship and Effect of HACCP on Current Inspection Procedures: To what extent will the possible changes in the regulated industry impact on possible changes in the current inspection system?

Discussion on this issue centered on five points: Modification of inspection procedures to take advantage of HACCP plans; advantages and disadvantages of continuing current regulatory programs until HACCP is fully implemented; ways to combine HACCP and the current inspection system; the extent to which changes in industry will affect changes in inspection; and the potential effects of HACCP on small establishments. Modification of inspection procedures to take advantage of HACCP plans generally follow NACMCF recommendations that regulatory verification of HACCP plans can be accomplished in lieu of, rather than adding to, existing procedures. This would permit reallocation of inspection resources to food safety concerns and away from quality attributes and aesthetic concerns. HACCP should not invite an arbitrary reduction in the inspection force and the numbers of inspectors should not be tied to HACCP implementation. The potential effects of HACCP on small establishments were noted, along with the view that some accommodation during implementation should be afforded to these establishments.

All issues raised and discussed during the HACCP Round Table were taken into account in formulating this proposal.

FSIS Experience With Process Control

(1) Current Application of Hazard Analysis to Meat and Poultry Processing.

The principle of hazard analysis has been utilized to prevent foodborne illness associated with specific meat and poultry products and to support regulatory process control for certain voluntary procedures. The examples discussed below represent FSIS's early efforts using hazard analysis to identify CCP's in a production process and to establish stringent regulatory requirements for controlling production processes. Whereas the earlier regulations were prescriptive, the current proposal is performance based, and holds the industry fully responsible for conducting the hazard analysis and identifying the CCP's and critical limits associated with producing products that minimize the risk of foodborne illness.

(a) Low-Acid Canned Foods

The low-acid canned food industry has had a remarkably good record over the past 50 years, during which more than 1 trillion cans of commercially canned foods were consumed. Beginning in 1970, however, botulinum toxin and *C. botulinum* were found in commercially canned product produced under the jurisdiction of both FDA and USDA. From 1970 until 1990, nine incidents of botulinum outbreaks occurred, resulting in death on six occasions. The products implicated included mushrooms, peppers, salmon, boned turkey, chicken vegetable soup, tuna, and bean salad.

In response to the botulism outbreaks, the canning industry identified CCPs that must be controlled and monitored to ensure that canning operations produce safe canned foods. For products under its jurisdiction, FDA in 1973 codified the CCPs into a good manufacturing practice regulation for thermally processed low-acid canned foods packed in hermetically sealed containers(21 CFR 110).

Since FDA's promulgation of that regulation (revised in 1978), the threat of botulism in canned product has been greatly reduced. While sporadic incidents continue, investigations of such incidents have attributed the causes to establishments' failure to comply with the regulation rather than inadequacies in the regulation.

To address problems in the canned meat and poultry industry, in 1986 FSIS promulgated HACCP-based low acid canned food regulations similar to those of the FDA. CCPs identified in those regulations were incorporated into the Agency's Performance Based Inspection System, so that inspectors' tasks include verification of establishments' compliance with the regulations. Incidents of foodborne illness involving canned meat and poultry products that occurred following the publication of the rules have been attributed to establishments' noncompliance with the regulations.

(b) Commercially Processed Cooked Roast Beef

Five outbreaks of salmonellosis associated with the consumption of commercially processed cooked beef products occurred in the northeastern United States from 1975 until 1981. These outbreaks resulting from five different serotypes of *Salmonella*, caused up to 200 reported cases of illness per incidence.

FSIS responded to the outbreaks by supervising the voluntary recall and destruction of thousands of pounds of affected product on a case-by-case basis. Additionally, whole, intact, cooked roast beef products from several establishments were sampled and found positive for salmonellae. As a result of the outbreaks, it became apparent that salmonellae contamination of cooked beef products needed to be addressed on an industry-wide basis.

In 1977, FSIS promulgated a regulation requiring that all cooked beef products be prepared by ''a cooking procedure that produces a minimum temperature of 145 degrees F in all parts of each roast'' to destroy any salmonellae that might be present. This regulation was amended in 1978 to provide alternate cooking times and temperatures to preserve the rare appearance of the product but still destroy all salmonellae. (See 9 CFR 381.17.)

During the summer of 1981, eight additional outbreaks of the disease were linked to the consumption of roast beef produced by four separate establishments in the northeastern United States.

Epidemiologic investigations revealed that inadequate cooking times and temperatures were not the major problems. A new regulation was implemented in 1983 that addressed the necessary handling, processing, cooling times and temperatures, and storage requirements to ensure the wholesomeness of cooked roast beef.

In total, the changes that evolved in the roast beef regulations represented a HACCP approach in identifying the CCP's in roast beef processing that must be monitored and controlled by an establishment to ensure production of unadulterated product. These HACCP-based CCP's have subsequently been incorporated into the FSIS-PBIS system for scheduling inspectors' tasks in establishments that produce cooked roast beef. Since 1983, no confirmed salmonellae outbreaks have been traced to commercially prepared roast beef.

(c) Uncured Cooked Meat Patties

In response to recent outbreaks of foodborne illness caused by *E. coli* 0157:H7, FSIS promulgated a rule dealing with the heat-processing, cooking, cooling, handling, and storage requirements for uncured meat patties. HACCP principles were used to identify CCP's, critical limits, and corrective actions; as a result, cooking times and temperatures, cooling requirements, sanitary handling and storage practices, and requirements for the handling of heating or cooling deviations were established. The CCP's identified in that rule have been incorporated into the Agency's PBIS for scheduling inspector tasks to ensure establishments' compliance with the regulations.

The ''Heat Processing Procedures, Cooking Instructions, Cooling, Handling and Storage Requirements for Uncured Meat Patties'' (8/2/93 at 58 FR 41151) incorporated HACCP concepts (CCPs, critical limits, corrective actions, etc.) associated with the manufacture of uncooked, partially cooked, char-marked, comminuted products.

(d) Current Process Control Systems

The development and implementation of standardized process control procedures, such as Total Quality Control (TQC) systems and Partial Quality Control (PQC) programs have been part of an effort to focus the responsibility for compliance on the processing establishment. FSIS first began approving industry operated quality control programs in the mid 1970's. The QC policy evolved throughout the late 1970's until in 1980 when it was codified in 9 CFR 318.4 and 381.145 providing a regulatory basis for FSIS policies for PQC and TQC. At present, there are over 9,000 approved PQC programs in operation in inspected establishments and 361 approved and operating TQC systems.

TQC systems are defined by regulation as plans or systems for controlling product after antemortem and postmortem inspection throughout all stages of preparation adequate to result in product being in compliance with the regulations (9 CFR 318.4(c) and 381.145(c)). This definition had traditionally been interpreted to mean that an establishment's TQC system must include control for all aspects of a process. By regulation, PQC programs may be approved for controlling the production of individual products, individual operations within the establishment, or parts of operations (9 CFR 318.4(d) and 381.145(d)).

In processing establishments, most approved PQC programs are designed to control economic and quality aspects of meat and poultry products, such as net weight and label claims. Such PQC programs are generally voluntary or are a condition of label approval. A smaller number of procedures operate to control product wholesomeness factors and are mandated in current regulations. These include the production of cooked roast beef (§ 318.17), mechanically deboned product (§ 319.5), and irradiated poultry product (§ 381.145). In addition, some PQC programs are approved as alternative procedures to regulatory requirements such as handling thermal processing deviations (§§ 318/381.308) and finished product inspections (§§ 318/381.309) of shelf stable canned

meat and poultry products. In slaughter establishments, PQC programs are designed to control economic, quality, and some product wholesomeness aspects of production. Such programs include finished product standards, preoperational sanitation and carcass presentation. All slaughter PQC programs are voluntary.

Preventive systems of process control have been formally employed in the slaughter of broilers and Cornish game hens since 1983, and in the slaughter of turkeys since 1984. These process control approaches are integral features of inspection systems known as the New Line Speed (NELS) inspection system for broilers and cornish game hens, and the New Turkey Inspection System (NTIS) for turkeys (9 CFR 381.76). Forty-five establishments operate under NELS today, and 27 establishments operate under NTIS.

Under these slaughter process control systems, the establishment demonstrates compliance with regulatory requirements by identifying the points in the slaughter process that are important to regulatory compliance. The establishment then sets realistic standards for these points, and observes them often enough to detect deviation from a standard before non-compliance occurs. The establishment also identifies action it will take if a standard is not met. The written program and the generated records of observations and actions are evidence of the degree of process control and regulatory compliance. By reviewing and evaluating establishment records and verifying them with process observations as necessary, FSIS inspection personnel ensure an establishment is meeting its responsibility to produce safe and wholesome product.

The principal difference between slaughter process control systems in place in NELS and NTIS establishments today, and the proposed HACCP system is the focus of the systems. NELS and NTIS were designed not only to address safety hazards associated with raw poultry carcasses, but quality factors as well. The proposed HACCP system focuses on hazards associated with safety of product.

International Efforts on HACCP

Between 1990 and 1992, a working group of the Codex Committee on Food Hygiene developed a guideline document that covered the principles and application of HACCP to all sectors of the food chain from producer to consumer. The Codex Alimentarius Commission in 1993 adopted the HACCP document that now serves as a benchmark for countries to incorporate HACCP principles into their food industries. The seven HACCP principles adopted by the Codex Alimentarius Commission are identical to those proposed in this rule with the exception that HACCP principles six (i.e., recordkeeping) and seven (i.e., verification) are reversed.

In 1993, Agriculture Canada implemented a Food Safety Enhancement Program, which is designed to encourage the adoption of HACCP principles across all agri-food processed commodity groups and shell eggs. The food industry will be required to control and monitor its manufacturing process and maintain records at CCP's. FSEP will also provide a means to help government inspectors prioritize their responsibilities and focus their attention on CCP's in the process to ensure the production of safe food. Full implementation of the FSEP program is scheduled to be completed by September 1996.

Recently, the European Union (EU) adopted two Directives that made reference to the HACCP system. One Directive (93/43/EEC) focuses on the hygiene of foodstuffs and specifies that food business operations must identify and control any step in their process critical for ensuring food safety using the HACCP system. The other Directive (92/5/EEC) is one specific to meat products, which also embraces HACCP principles. These Directives were adopted on June 14, 1993 and February 10, 1992, respectively. EU members have up to 30 months from the date of adoption to implement the provisions of the Directives into national law. Detailed guidelines are now under development for meat products.

New Zealand has also been proactive in adopting HACCP principles in the food industry. Through the publication of *Guide to the Implementation of Hazard Analysis and Critical Control Point Systems in the Meat Industry*, the Ministry of Agriculture and Fisheries provided: (1) a generic model from which an understanding of the HACCP approach to food safety can be obtained; (2) a guide to the application of HACCP systems, especially in the case of raw foods; and (3) specific examples of application.

Adopting a HACCP system could potentially enhance international trade opportunities for the United States. Although enhancing trade has no direct effect on public health, participation in international trade in food products is critical to the U.S. economy. The United States is by far the world's major food exporter, with exports of raw agricultural and processed food products of over $40 billion per year. The United States also imports a substantial quantity of food products each year from many countries around the world. HACCP will improve FSIS's ability to monitor imports and thus ensure greater confidence in their safety. Also, HACCP is becoming the world-wide standard to ensure the safety of food and will thus serve as the basis for harmonizing U.S. food safety regulations with those of other nations.

The Uruguay Round Negotiations under the General Agreement on Tariffs and Trade (GATT) has resulted in further focus on this area. The Agreement on the Application of Sanitary and Phytosanitary Measures states the desire of member countries including the United States, to further ''* * * the use of harmonized sanitary and phytosanitary measures between members, on the basis of international standards, guidelines, and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission * * *''. This trend toward harmonization coupled with the current recommendations of the Codex Alimentarius Commission encouraging the international use of HACCP, provide further support for FSIS's proposal for a mandatory HACCP program for the production of all meat and poultry products.

FSIS Guidance on Development of HACCP Plans

FSIS believes that it can facilitate development of HACCP plans in various ways without compromising the principle that these are industry process control plans and, as such, plan development is the responsibility of the regulated establishment. Therefore, FSIS has underway a series of planned assistance efforts, which will continue and be completed over the next 6–12 months.

(a) Generic Models: FSIS has published the generic models developed at Agency workshops and will publish generic models developed by NACMCF as they become available. An example, the ''Generic HACCP for Raw Beef,'' is provided in the Appendix.

FSIS has categorized in this proposed regulation all processes carried out in the establishments it regulates. Because FSIS pilot-testing has shown generic plans to be useful to establishments as they develop plans specific to their own processes and products, FSIS will publish and make widely available a generic model for each of the nine process categories at least six months in advance of the due date for each process category. FSIS believes that use of

generic plans will assist in assuring the basic level of uniformity necessary to have inspection activities based on establishment HACCP plans, and that the provision of generic models will help to communicate the level of detail expected in the elements of the plan. FSIS also believes that generic models can help identify the kinds of hazards that should be considered at various CCP's, without interfering with the establishment's hazard analysis.

(b) NACMCF Materials: FSIS is publishing and will make widely available guidance materials developed by NACMCF describing the optimum steps to be followed in developing HACCP plans. In addition, FSIS is currently exploring the most effective and economical approach to developing a HACCP videotape.

(c) Computer Packages: FSIS is aware of commercially available software programs that might assist food processors in developing HACCP plans. FSIS has made a commitment to work with companies developing these programs to make them more applicable to meat and poultry processes.

2. Discussion of HACCP Proposal Regulatory Considerations

Process control is neither FSIS's responsibility nor a shared responsibility between the Agency and industry. Each USDA inspected establishment must assume full responsibility for making safe and wholesome products. FSIS is responsible for assuring that products in marketplace distribution are unadulterated, wholesome, and accurately labeled. From a public health perspective, the more that industry process controls anticipate and prevent problems, the less likely products produced under such systems are to become adulterated.

HACCP is not an inspection system; it is an industry process control system that provides opportunities to make inspection more effective. Currently, FSIS performs inspection by having inspectors generate information about the establishment's production process and environment to evaluate the conditions under which meat and poultry products are being produced. This activity permits oversight of establishment efforts at the time of inspection. In contrast to this relatively small amount of information, HACCP records will enable inspectors to see how the establishment's processes have operated on a continuing basis over time. The Program employee will be able to determine whether problems have occurred and, if so, how they were addressed.

In addition to providing a greater quantity of information and in effect extending the scope of regulatory observations, the presence of functional HACCP plans for all products and processes will also produce more relevant data. This is because the monitoring and recordkeeping requirements of a HACCP plan are organized around identified hazards, CCP's, critical limits, and the actions taken to ensure that defects are corrected before they become a risk. Finally, HACCP systems will yield data that are more objective and more scientific.

(1) Definitions

For the purposes of this discussion and within this proposed rule, FSIS has adopted some definitions of terms related to HACCP and HACCP systems from the NACMCF in the publication titled ''Hazard Analysis and Critical Control Point System,'' dated March 20, 1992; these definitions are noted by ''*''. Other definitions are specific to FSIS and its activities.

Corrective action. Procedures to be followed when a deviation occurs.*

Criterion. A requirement on which a judgment or decision can be based.*

Critical Control Point (CCP). A point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.*

Critical Control Point (CCP) failure. Inadequate control at a CCP resulting in an unacceptable risk of a hazard.

Critical limit. A criterion that must be met for each preventive measure associated with a CCP.*

Deviation. Failure to meet a critical limit.*

HACCP. A hazard analysis and critical control point system (HACCP) that identifies specific hazards and preventive measures for their control to ensure the safety of food.

HACCP plan. The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.*

HACCP-trained individual. A person who has successfully completed a recognized HACCP course in the application of HACCP principles to meat and poultry processing operations, and who is employed by the establishment. A HACCP-trained individual must have sufficient experience and training in the technical aspects of food processing and the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question.

HACCP system. The result of the implementation of the HACCP plan.*

Hazard. A biological, chemical, or physical property that may cause a food to be unsafe for consumption.*

Hazard Analysis. The identification of any biological, chemical, or physical properties in raw materials and processing steps and an assessment of their likely occurrence and seriousness to cause the food to be unsafe for consumption.

Monitor. To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.*

Preventive measures. Physical, chemical, or other factors that can be used to control an identified health hazard.*

Process. A procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products wherein all CCP's are identical, except that optional operations or CCP's, such as packaging, may be applied to one or more of those products within the group.

Product. Any carcass, meat, meat byproduct, or meat food product, poultry, or poultry food product capable of use as human food.

Recognized HACCP course. A HACCP course available to meat and poultry industry employees, which satisfies the following: consists of at least three days, one day devoted to understanding the seven principles of HACCP, one day devoted to applying these concepts to this and other regulatory requirements of FSIS, and one day devoted to beginning development of a HACCP plan for a specified process.

Responsible Establishment Official. The management official located on-site at the establishment who is responsible for the establishment's compliance with this part.

Validation. An analysis of verification procedures, HACCP plan components, and an evaluation of records associated with the HACCP system to determine its efficacy for the production of wholesome product for which the process was designed.

Verification. The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.*

(2) HACCP Plans

(a) Basis of Required Elements

The question of adherence to the seven principles of HACCP as defined by the NACMCF has been considered by FSIS since it began HACCP activities.

FSIS has determined that the scientific and conceptual integrity of HACCP as articulated by NACMCF is critical to its success and to public acceptance of inspection systems based on it. FSIS believes that each principle is important to achieving the objectives of HACCP and that the support of the scientific, technical, and industry communities for HACCP rests on its overall integrity. Furthermore, the external advice from such bodies as NAS and GAO recommending HACCP implementation assumed adoption of all seven principles. Therefore, the Agency has determined that its regulatory requirements will be founded on HACCP principles as articulated by NACMCF. Comments are invited on this fundamental premise of the FSIS proposed regulation.

(b) Required Elements

FSIS is proposing to require that inspected establishments develop HACCP plans that include: identification of the processing steps that present hazards; identification and description of the CCP for each identified hazard; specification of the critical limit, which may not be exceeded at the CCP and, if appropriate, a target limit; description of the establishment monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded and the individual responsible for taking corrective action; description of the records that will be generated and maintained regarding this CCP; and description of the establishment verification activities and the frequency at which they are to be conducted. Critical limits currently a part of FSIS regulation or other requirements must be met. FSIS invites comment on permitting approval of alternative procedures if sound scientific reasons and data are provided.

FSIS is proposing that the HACCP plan be signed by the responsible establishment official as an indication of his or her accountability for the plan. Comment is invited on the merits of such a requirement as a method of ensuring and demonstrating establishment commitment to, and formal adoption of, the plan.

(3) Overview of Plan Content and Format; Consistency With FDA

FSIS is aware that a large number of food producing companies are regulated by both FDA and USDA. Earlier this year, FDA proposed to mandate HACCP for seafood processors (59 FR 4142, January 28, 1994). In formulating the proposal presented in this document, FSIS has tried to assure conceptual uniformity and consistency with FDA on the practical details to the greatest extent possible. However, differing statutes are administered by the two agencies and each species—livestock, birds and fish and shellfish—differ significantly.

In many important respects, the FSIS and FDA HACCP programs are fully consistent. The same underlying principles of HACCP form the foundation of the two programs. Both programs have the goal of improving the microbial profile of regulated food products and, thereby, reducing the incidence of foodborne illness that might be associated with these foods.

Both programs require that establishments: develop HACCP plans that address the health and safety aspects of their processes; have access to at least one HACCP-trained individual; and recognize and carry out their responsibility to control sanitation as a prerequisite to HACCP.

In addition, both regulatory programs are similar in that operational success is the mechanism for acceptance of establishment HACCP plans; verification tasks of all types will be conducted by regulatory officials; and FSIS and FDA will attempt to provide assistance to establishments through the development of guidance materials or generic models from which industry efforts can begin.

FSIS is recommending that the format used in its generic models and those of the NACMCF be followed by all establishments; however, Agency personnel will be flexible in this matter and consider alternative formats that ensure that both establishment and inspection personnel can readily identify the hazards, the CCP's and the specific critical limits, plus actions and records that should be associated with each. The generic models are to provide guidance, not serve as blueprints, and not substitute for process controls. FSIS proposes to publish and make widely available both its generic models and the NACMCF models. Comments are invited on this approach.

FSIS is proposing to require that each inspected establishment have and implement a HACCP plan that is specific to each kind of meat or poultry processing activity conducted in that establishment. Establishments coming under inspection after the implementation date appropriate for the process(es) to be conducted will be required to develop their HACCP plans in conjunction with the application for the grant of inspection. FSIS acknowledges that such establishments may need some practical experience operating under their HACCP plan to finalize their plans. FSIS invites comments on whether new establishments coming under inspection should be granted a reasonable amount of time, for example, six months, to finalize their HACCP plans under commercial conditions.

(4) Sanitation as a Prerequisite to HACCP Plan Development

FSIS believes that there are certain prerequisites that must be met before successful HACCP plan development can be accomplished. An important foundation is the successful control of the cleanliness and sanitation of the facilities and equipment, and adequacy of employee sanitation and hygienic practices necessary in producing meat and poultry products. FSIS is proposing that this be accomplished through Standard Operating Procedures for sanitation. (See ''Near-term Interventions'' section of ''DISCUSSION OF REGULATORY PROPOSALS,'' above).

These proposed regulations reflect the decision that HACCP plans should address food safety factors only. FSIS invites comment on this approach.

(5) Participation of HACCP-Trained Individuals

The Agency believes that establishments will vary widely in their familiarity and experience with HACCP. All establishments will need to have access to persons who have been trained in HACCP and its application to meat and poultry production processes. Some establishments have already chosen to secure HACCP training for their staff or to secure consulting services. Others must accomplish this before they begin the hazard analysis that will initiate their plan development process. FSIS will consider an individual who has successfully completed a recognized HACCP training course, as defined in §§ 326.1 and 381.601, to be a HACCP-trained individual.

A recognized HACCP course would consist of at least three days: one day devoted to understanding the seven principles of HACCP; one day devoted to meshing these concepts with this and other regulatory requirements of FSIS; and one day devoted to development of

a HACCP plan for a specified process. As discussed below, the Agency expects that many organizations will be knowledgeable about such courses and may serve as legitimate sources of such training. It is the responsibility of the establishment sending its employee(s) to a particular training course to ascertain that the course meets the minimum requirements described above.

FSIS is aware that, through industry-sponsored training courses, several hundred industry employees have already received the necessary training. It is not expected that such training needs to be repeated. Individuals who previously received HACCP training should be able to supplement their knowledge through guidelines and informational materials made available by FSIS, NACMCF, professional associations, and trade associations. FSIS invites comments on this approach for supplementing knowledge levels of previously trained individuals. In cases where a consulting expert serves as the HACCP-trained individual for an establishment, it is the responsibility of the establishment to assure that this individual has the requisite training.

FSIS is also proposing that the HACCP-trained individual participate in the hazard analysis and subsequent development of the HACCP plans, and assist in addressing product safety in situations where there have been deviations from critical limits and judgment is needed to determine the adequacy of the response. HACCP-trained individuals must also be available to establishments to participate in plan modification and revalidation. FSIS does not believe it needs to prescribe details about the hours or days on which the HACCP-trained individual is to be on establishment premises, or what should be done in establishments having multi-shift operations, other than to require that the HACCP-trained individual be available to the establishment to accomplish the prescribed role. FSIS is proposing that the establishment have on file the name and a brief resume of the HACCP-trained individual on whom it is relying.

The Agency has determined that a HACCP-trained individual must be employed by each establishment. This individual will be responsible for addressing and performing functions related to hazard analysis, plan development, plan validation, review and assessment of critical limits, and responses to deviations. The HACCP trained individual will be pivotal in an establishment's ability to successfully assure process control in an operational HACCP system. The Agency recognizes that employment of a HACCP trained individual could also be accomplished through acquisition of the services of a HACCP consultant. The Agency does not intend to be overly prescriptive by specifying the conditions of employment between the establishment and the HACCP trained individual. It is, however, the determination of the Agency that the services of a HACCP-trained individual able to carry out the activities described above is essential to successful operation of a HACCP system. Comments are invited on this approach.

This proposed requirement for involvement by a HACCP-trained individual is an alternative to requiring that there be such an individual in each establishment. FSIS recognizes that, for many establishments, securing HACCP expertise by training one employee in a recognized HACCP course is the best means to meet this requirement. Comments are invited on this approach.

(6) Hazard Analysis

FSIS believes that success in HACCP plan development is founded on a hazard analysis that is thorough and forces the establishment to critically think about and analyze its processes. Guidance materials prepared by the NACMCF for carrying out Principle 1 address this issue. Especially for establishments without HACCP experience, this is a critical and challenging first step. Because FSIS is concerned that each establishment properly begin its application of the concepts of HACCP, the Agency is proposing to specify a time frame prior to the due date for any HACCP plan, during which hazard analysis should be conducted.

The proposed time frame is six months; this means that six months before any HACCP plan is required to be completed, establishments should begin the hazard analysis process. Activities constituting the hazard analysis include: accurately and completely describing product composition, developing a flow diagram, listing of all hazards associated with each processing step, and collecting of necessary scientific data to assess and validate the effectiveness and variability of process controls. During the six-month hazard analysis period, there should be regular meetings between inspection personnel and the establishment HACCP team on the subject of the hazard analysis.

Once the hazard analysis has been completed, it is expected that identification of CCP's will begin and the activities related to the remaining principles will be carried out so that the plan can be ready and validated by the due date.

In only one circumstance will Program employees be expected to report on the progress of these establishment activities with respect to plan development; that is, if there has been no effort to initiate hazard analysis, and the subsequent application of remaining HACCP principles, at least one month prior to the due date for the HACCP plan. FSIS believes that, in such a circumstance, there is a considerable likelihood that the plan will be insufficient and that regulatory action will be necessary. Therefore, Program employees will report such a situation through their supervisory channels. FSIS invites comment on this particular feature of the proposed implementation schedule.

(7) Establishment-Specific HACCP Plan Acceptance

The question of HACCP plan acceptance has been long and thoroughly considered by the Agency. In reviewing various options, the Agency has maintained several objectives:

- Any acceptance system should not include a requirement that HACCP plans be physically forwarded to the Agency and remain in its possession at one or a few central locations.
- The acceptance system must accommodate varying establishment-specific HACCP plans for similar products, but maintain uniformity on basic standards.
- The acceptance system should involve Agency in-plant Program employees to the maximum extent possible, after they have been provided the requisite education and training in HACCP.

The Agency gave serious consideration to requiring formal plan acceptance prior to full plan operation, either by formal FSIS approval or by an ''expert'' computer system. However, advice from colleagues at FDA suggested that any system of acceptance prior to operational validation was likely to be administratively complex and irrelevant to successful implementation. Therefore, the Agency has decided that plan acceptance will not be a one-time administrative event but a process. Successful process control, as evidenced by the existence of a plan having all the features required by the seven principles plus the capacity of the plan to result in production of complying products, will mean that the plan is acceptable.

Inspection activities will be designed to verify that the plan has all the required features, that the plan and the

records it generates are a reflection of what has occurred during processing of products, that deviations have elicited appropriate responses, and that continually complying products have been produced. Whenever any of these conditions are not met, the plan will be judged to need revision and revalidation.

In essence, establishment-specific HACCP plans will be developed, reviewed, and validated at the establishment level on a continuing basis, with activities by both establishment and Program employees. This has emerged as the most viable and efficient approach for both the Agency and industry.

Responding to Deviations From Critical Limits

FSIS is proposing to require that deviations from critical limits trigger a prescribed set of actions by an establishment.

First, under this proposed provision, product affected by the deviation from the critical limit must be segregated and held until the significance of the deviation can be determined. Second, the establishment must make the necessary determination of the effect of the deviation on product safety. This determination must be made in consultation with a HACCP-trained individual and any other subject-matter experts needed to deal with the deviation in question. In consultation with this person or team, the establishment should also determine whether the deviation reveals the need to modify either the process itself or the HACCP plan.

Finally, FSIS is proposing to require that establishments record all steps taken in response to a deviation from a critical limit and include that information as part of the HACCP record. Documentation of deviations should be brought to the attention of FSIS personnel.

HACCP Recordkeeping

Maintenance of accurate HACCP records is fundamental to a HACCP system and is the cornerstone of its usefulness to regulators. Therefore, FSIS is proposing to require that these records contain certain necessary information; that the records be systematically reviewed by the establishment; that the records be maintained for a specific period of time; and that FSIS Program personnel be given access to these records.

First, FSIS is proposing that the records involving measurements during slaughter and processing, corrective actions, verification check results, and related activities contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The purpose of this proposed requirement is to assure that both the establishment and the regulator can readily link a record to a product and the period during which the product was processed. FSIS is also proposing to require that the information be recorded at the time that it is observed and that the record be signed by the operator or observer.

Second, FSIS is proposing to require that the HACCP records associated with the product to be shipped be reviewed by an establishment employee other than the one who produced the record, before the product is distributed in commerce. The purpose of this review is to verify that the HACCP system has been in operation during the production of the product, that it has functioned as designed, and that the establishment is taking full responsibility for the product meeting applicable food safety regulatory requirements. If a HACCP-trained individual is on-site, that person should be this second reviewer. The reviewer should sign the records. FSIS program personnel will be performing similar reviews of HACCP records on a regular basis, but their oversight cannot be substituted for the establishment's review.

Third, FSIS is proposing that HACCP records generated by the establishment be retained on site for at least one year and for an additional two years on-site or at another location. HACCP records will be necessary in the revalidation process. Further, FSIS' experience with other recordkeeping requirements indicates this is a manageable time frame. FSIS invites comments on the appropriateness of these records retention requirements.

Finally, FSIS is proposing to require that HACCP plans and records be available for review and copying by program personnel at reasonable times. Industry records are reviewed by Program personnel as part of their assigned tasks. Comprehensive records access is necessary to permit verification of all aspects of a HACCP system. However, FSIS does not intend to routinely copy or take possession of such records. It is the Agency's intent to generate its own records of its verification tasks and results rather than duplicate the records of the establishment. Data collection instruments for program employee verification tasks are being developed and will become the Agency's verification record that the HACCP system is functioning as intended.

Extensive copying of records is anticipated only in cases where there was evidence of non-compliance with requirements or deviations from critical limits that resulted in product safety problems. In such instances, complete access to all pertinent records would be necessary. FSIS invites comments on this issue.

Training

There is significant interest by the Agency in HACCP training for Agency and industry personnel. FSIS takes full responsibility for the training of its own personnel within time frames that permit the orderly implementation of HACCP. The Agency's interest in HACCP training for the regulated industry is based on the need to assure that both industry and Agency personnel are receiving training that is founded on a single vision of HACCP and how it is to operate.

Two areas concerning training requirements were considered by the Agency in determining how training for HACCP-trained individuals should be evaluated: The availability of training and whether to require acceptance or accreditation for training programs.

Upon review the Agency determined that there are a number of options for the industry when selecting the appropriate training course for their employee(s). Among these are courses offered by industry trade associations, such as AMI, the National Food Processors' Association, and others. Academia also offers courses in HACCP principles and application. Groups such as the HACCP Alliance, The National Center for Food Safety and Technology, and accredited universities are among the available sources for HACCP training. Private consultants and consulting firms also offer HACCP training. Other available resources include a list of HACCP courses prepared by USDA's Extension Service. These training sources are all available to the regulated industry although the cost, length, and to some extent, the content of these courses differ. Recognizing that there are differing needs for technical knowledge and ability to pay for these courses among the regulated industry, FSIS has determined that each responsible establishment official should be responsible for deciding which provider of training best meets the establishment's needs.

A second concern is whether the Agency should stipulate that the courses taken by a HACCP-trained individual be subject to acceptance or accreditation. This accreditation could be conducted by the Agency, by an outside body (e.g.,

scientific body or professional association) under the auspices of an industry-sponsored accreditation system, or a decision to require no accreditation for courses could be adopted. An outside source for accreditation could be created by the industry as is the case in thermal processing where a nationally recognized course is offered by industry. A scientific body or a professional association could serve such a function.

FSIS considered the implications of serving as an accrediting body for HACCP training courses. This option afforded three choices. First, the Agency could provide accreditation review of all available HACCP courses. This could be accomplished by contracting out the function. Second, the Agency could provide this service to the regulated industry through staff resources. This would require a significant diversion of Agency resources from regulatory activities to servicing the industry by approving a large volume of requests for review of HACCP courses. Third, FSIS could publish a periodic list of unacceptable HACCP courses based on the training received by HACCP-trained individuals in establishments with proven histories of poor performance. This would serve only to identify those courses the Agency determined through establishment performance to be inadequate preparation for a HACCP-trained individual.

To assure that training is timely, to reduce cost requirements for the Agency and industry, and to assure that a wide range of options is available to the industry, the Agency has tentatively concluded that the adequacy of courses for a HACCP-trained individual should be evaluated by each responsible establishment official. FSIS is not proposing to establish an accreditation process to evaluate training courses, because the Agency believes that its evaluation of the establishment's HACCP performance is the most resource-efficient means to reveal any training deficiencies or mistakes in the course selections made by the establishment. The Agency is soliciting comment on this approach and will consider other viable options for ensuring appropriate training of industry personnel.

Implementation Schedule

Since mandatory HACCP was first considered by FSIS, the Agency has been considering the significant issues surrounding orderly implementation. Public discussions regarding phase-in have alternated between the need for caution in implementing so significant a change too quickly and a sense of urgency because of the food safety benefits associated with HACCP. The time frame for implementation in these proposed regulations attempts to balance these competing concerns. The first phase-in of a process begins 12 months from the publication of the final rule and ends at 36 months. This balanced phase-in approach will permit the regulated industry time to accomplish the training of personnel and adjust their activities to include necessary HACCP activities.

FSIS proposes to establish a timetable for phasing in HACCP based on industry production process categories. In identifying process categories for phase-in of mandatory HACCP, the Agency has taken a number of factors into account. These include the knowledge of areas where controls similar to HACCP presently exist; consideration of all activities conducted by regulated establishments; consideration of the wide variety of products produced by the regulated industry that are difficult to sort into separate product categories; and the nature of changing and constant product development activities conducted by the industry. Also in keeping with the process control principles inherent in HACCP, FSIS has selected process as the basis for phase-in, rather than product category. The Agency has identified process categories that appear to encompass all the processes of the regulated industry. They are:

01 Raw, Ground: This category includes ground red meat (beef, pork, sheep, etc.), ground poultry, all mechanically separated species, and mechanically deboned poultry.

02 Raw, Other: This category includes all red meat species and poultry classes not fully cooked including non-intact muscle products (shaped, formed, separated, etc.), all intact raw muscle products including processed (injected, coated, breaded, tenderized, etc.) and all cut, or boned product both bone-in and boneless.

03 Thermally Processed/ Commercially Sterile: Included in this category are retortable pouches and canned meat and poultry products.

04 All Other Shelf Stable, Not Heat Treated: This category includes all products that are shelf stable including dried, controlled by water activity, pH, dehydrated, freeze dried, fermented, and products that meet the requirement for a maximum pH of 4.6, for example freeze dried soup or meals, shelf stable salami, jerky, or dried beef.

05 Fully Cooked, Not Shelf Stable: This includes all keep refrigerated or frozen products including those that are sliced and packaged, and products prepared by central kitchens, for example cooked sausage, hams, frozen fully cooked beef patties, pizzas.

06 All Other Shelf Stable, Heat Treated Product: This includes rendered products, for example lard and oils.

07 All Non-Shelf Stable, Heat Treated, Not Fully Cooked Product: This category includes ready-to-cook poultry, cold smoked and products smoked as a trichinae treatment, partially cooked, battered, breaded, char-marked, batter set, and low temperature rendered products, for example partially cooked patties and nuggets, partially defatted beef, ready-to-cook barbecued chicken, mettwurst, etc.

08 Non-Shelf Stable, with Secondary Inhibitors: This includes products that are irradiated, fermented, salted, and brine treated, for example, oriental sausages, pressed duck, and irradiated poultry.

09 Slaughter: This includes all red meat species, all poultry classes, and all voluntarily inspected species and classes.

Special considerations for phasing HACCP into small establishments are discussed below.

The proposed effective dates for each category are expressed in relation to publication of a final HACCP regulation; the six month Hazard Analysis period is to precede the effective date for each process category.

In determining the phase-in sequence for these categories, four options were considered.

The first proposed phase-in option considered is based on the public health and safety risk inherent in the production process. Risk considerations dictate that raw ground product be in the initial implementation period, followed by slaughter since these processes result in products that have been shown to pose the greatest risk for foodborne illness. The process categories were then ranked according to the food safety process controls applied during the manufacturing process. This option would have phased-in Shelf Stable, Heat Treated and Thermally Processed/Commercially Sterile processes in the final groups. Those processes include areas in which significant interventions take place during production to assure product safety.

The second option considered the controls that currently exist in regulation mandating critical control points and critical limits related to health and safety. This method would have phased-in those processes where the greatest process control experience and regulatory standards exist for the earliest implementation dates. The

burden for the development of a HACCP plan and hazard analysis would not have been as great for these establishments due to past experience. This option would initially have phased-in processes such as Thermally Processed/Commercially Sterile and end with Raw, Ground; Raw, Other, and Slaughter processes. Phase-in would occur in an inverse order from the first option considered.

The third phase-in scenario considered by the Agency utilized an evaluation of the number of establishments producing products covered by a process and the known volumes of industry production for each of these processes. In this option, process category Raw, Other would have been implemented first since this comprises a large sector of industry production both by volume and the number of producing establishments. The second process for phase-in would have been slaughter, since again, this comprises a large portion of the regulated industry both in the number of establishments and the volume of product produced. Thermally Processed/Commercially Sterile would have been the final process phased-in under this option since this process constitutes a small segment of the regulated industry both in the number of producing establishments and the volume of production.

The fourth option for phase-in, and the one proposed by the Agency, incorporates considerations from each of the above-discussed options, beginning with the processes that constitute the greatest public health risks, combining some other processes where the volume of production in the regulated industry is lower, using the option for processes where a large body of experience and regulatory criteria presently exist, and combining these for the existing time frame of total implementation over a 1-to-3-year period from the publication of a final HACCP regulation. In all options considered, the category encompassing small establishments will be phased-in last. FSIS selected the fourth option because it takes into consideration production, experience with process control, and public health risk. FSIS invites comments on the proposed phase-in schedule.

The Agency envisions that, upon the required implementation date for phase-in, establishments will be completely ready to operate their HACCP system and that FSIS will conduct inspection activities according to HACCP principles, including verification and validation, to ensure that the HACCP system as operating is acceptable.

The proposed phase-in schedule 4 is as follows:

Final rule plus 12 months: Raw Ground; Thermally Processed/ Commercially Sterile; and all Other Shelf Stable, Heat Treated Products.

Final rule plus 18 months: All Non Shelf Stable, Heat Treated, Not Fully Cooked; all Other Shelf Stable, Non Heat Treated.

Final rule plus 24 months: Fully Cooked, Non Shelf Stable; all Non Shelf Stable with Secondary Inhibitors.

Final rule plus 30 months: All Slaughter; all Raw Other Product.

Final rule plus 36 months: Small Establishments.

Special Consideration for Small Establishments

FSIS believes that planned technical assistance activities offer benefits to small establishments. Among these are the provision of generic models from which to begin HACCP plan development and the provision of other guidance material. Additionally, FSIS is proposing that small establishments, regardless of the processes performed and products produced, be permitted 36 months from the date of publication of the final rule in the **Federal Register** to complete plan development. In determining which establishments should be eligible for this implementation schedule, FSIS considered three ways of defining ''small.'' The object was to distribute the economic burden equitably among various segments of the industry.

(1) Defining ''small'' on the basis of units produced (number of head slaughtered, number of birds slaughtered, or pounds of product produced). Because of the difficulty of making meaningful economic comparisons among unlike species and processes, the Agency decided against defining small establishments on the basis of production volume.

(2) Defining ''small'' according to the number of establishment employees. The Agency rejected this approach because the number of employees is not a good indicator of the ability of the establishment to undertake additional financial burdens.

(3) Definitions based on annual sales in dollars. This simple, across-the board measure appears both reasonable, simple, and fair. For this reason, the Agency selected this approach, rather than either of the others discussed, alone or in combination.

For the purposes of HACCP implementation scheduling, FSIS is proposing that small establishments be defined as those with annual production valued at or below $2.5 million. Defining a small business as one with a maximum of $2.5 million in annual sales allows the maximum time for compliance with the HACCP requirement for a significant number of establishments, with approximately one-third of all establishments falling into the ''small'' category. Further, using the amount of $2.5 million the percentage of slaughter establishments considered small is roughly the same as the percentage of processing establishments falling into this category. The proposed definition of a small establishment will not significantly affect achievement of the Agency's food safety objectives, because slaughter and processing establishments in this category together account for less than one percent of annual meat and poultry production in the United States.

FSIS invites comment on its approach to defining small establishments.

Regulatory Oversight of the HACCP System

The NACMCF has specifically addressed the subject of the roles of regulatory agencies with respect to establishments in which HACCP is the system of process control for food safety (''The Role of Regulatory Agencies and Industry in HACCP''). FSIS is in general agreement with that discussion, especially the part that emphasizes that, with respect to food safety, establishments must operate effective HACCP systems and the government role should focus on verification that HACCP plans are working as intended. If the regulatory agency were to take on hazard identification, determination of CCP's or critical limits, responsibility for corrective actions or monitoring responsibilities, it would be undermining the need for the establishment to assume full responsibility for the processing of safe product through the HACCP system of process control.

Verification procedures the Agency might use include:

(1) Review of the HACCP plan;
(2) Review of CCP records;
(3) Review of deviations and responses to deviations;
(4) Visual inspections of operations to see if CCP's are under control;
(5) Random sample collection and analysis (including microbial testing);
(6) Review of critical limits;
(7) Review of written records of establishment verification tasks;
(8) Revalidation of HACCP plans including on-site observations and complete records review.

FSIS intends to review and revise existing inspection tasks to assure that

they are focused on the CCP's for each of the processes that will be controlled by HACCP plans. These revised tasks will be incorporated into the PBIS and become part of regular assignments for program personnel.

Public Access to Records

There is a broad policy question about public access to establishment records generated under HACCP. Some groups believe that any records used by regulatory agencies for making a determination about the safety of meat and poultry products produced should be made public to the maximum extent possible. Others take the position that such broad-scale access compromises establishments' rights to protect sensitive commercial information from business competitors.

FSIS believes that public access to any records which it generates itself and any establishment records copied by FSIS as part of its verification tasks would be governed by the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the implementing regulations of USDA (7 CFR Part 1, Subpart A). FOIA exempts particular commercial and financial information from mandatory release by government agencies. As a preliminary matter, it appears that at least some elements of HACCP plans and monitoring records would be considered commercial information of the kind exempt from disclosure. FSIS is committed to meeting fully the public disclosure objectives and requirements of the Freedom of Information Act.

It should be noted that the FOIA presumes that the governmental agency has both possession and control of the record. Therefore, when information is obtained from an establishment and is maintained by FSIS, that information becomes an agency record subject to FOIA. As previously discussed, the Agency is not proposing that HACCP plans be submitted for approval. HACCP plans which have been accepted by virtue of successful process controls will be on file in the establishment and available for review by FSIS program personnel. Therefore, the information maintained by the establishments, including monitoring records, would not be subject to a FOIA request. However, if during validation of an establishment's HACCP plan, or during an investigation of an alleged violation, HACCP records are obtained from an establishment, those records become agency records subject to FOIA.

FSIS invites public comment on the issue of whether broader public accessibility to an establishment's records is in the public interest, and, if so, to what extent the records should be required to be disclosed.

Relationship to Other Process Control Systems

To eliminate duplication, redundancy, and confusion, FSIS is considering proposing that the mandatory HACCP plan become the only Agency recognized process control system for health and safety aspects of the processes/products of each establishment. Those portions of existing TQC systems or PQC programs that address health and safety issues would be encompassed within the mandatory HACCP plan. Those aspects of an establishments operations that are not health-and-safety related and, therefore, not covered by the HACCP plan would be monitored by tasks assigned through PBIS at frequencies determined by the demands of HACCP verification activities. Comments are invited on this approach.

Enforcement

The enforcement provisions would require that establishments have verified HACCP plans for their processing operations by the dates specified for the establishment and process. As noted, the HACCP requirements would be phased in by having different effective dates—12 months, 18 months, 24 months, 30 months, or 36 months from the date the final rule is published, depending on the establishment and the product(s) being produced.

Establishments that fail to have a verified HACCP plan in place for a processing operation by the date required for that operation would have its inspection for that process suspended. Similarly, new establishments and establishments applying for inspection of new processing operations would be denied inspection services after those dates unless and until a HACCP plan is in place for that process.

The enforcement provisions also provide that, once adopted, HACCP plans would still be subject to verification by FSIS. If a HACCP plan is found by FSIS to be invalid, inspection would be suspended from existing operations, pending correction of the HACCP plan.

A HACCP plan might be found invalid for one or more of three reasons: (1) The HACCP plan does not meet the essential requirements set forth in the regulation; (2) HACCP records are not being maintained as required by the regulation and/or the plan, preventing validation of the plan and/or verification of process controls as may be required, and (3) a processing failure results in the production of adulterated product.

Suspension of all or a part of an establishment's inspection services will be made under rules of practice, proposed in Part 335 of the Federal meat inspection regulations and Subpart W of the poultry products inspection regulations, requiring notice by FSIS to the establishment of the reasons for the suspension. The notice also would specify the processing operations affected (if not the entire establishment) and the corrective action(s) required before inspection service would be resumed.

While inspection is suspended, the facilities identified in the suspension notice could not be used for the production of meat or poultry products. Furthermore, if product produced prior to the suspension were suspected of being adulterated, such product would be retained at the establishment pending disposition by the Program, and if already shipped, such product would be subject to recall as necessary to protect public health.

A suspension would be lifted and inspection service restored upon the designated Program official providing written acknowledgement of receipt of a modified plan, coupled with a detailed validation of that plan by a HACCP-trained individual. The modified plan must have been developed in consultation with that HACCP-trained individual. In the case of suspension caused by a processing deficiency resulting in production of adulterated product, a written testing plan would also be required. The plan must provide for the testing of finished product produced under the modified plan for chemical or microbial characteristics, as appropriate, to demonstrate that the process under the modified plan would correct the identified problem.

Failure to prepare a valid HACCP plan as specified in the notice, by the time specified in the notice, will result in service on the establishment of a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service will be refused or withdrawn pending resolution of any hearing.

Failure to adhere to a modified HACCP plan, and, if applicable, testing plan, resulting in a repeat of the suspension for the same or a related deficiency, would in addition to the requirement for another modified plan, require a Program review of the establishment's performance under other provisions of the inspection laws before inspection would be restored.

Recurring violations of fundamental HACCP requirements would be viewed as indicating an increased likelihood that other violations of inspection requirements exist and that additional enforcement actions may be required by FSIS.

Finally, in the event the Administrator finds that HACCP records have been deliberately falsified, the Agency would in addition to any suspension in effect, issue a complaint for withdrawal of inspection from the establishment and would refer the case to the Department of Justice for criminal prosecution.

3. Illustrations of the Application of HACCP

The HACCP approach to process control is systematic and establishment specific. The generic models prepared by FSIS and NACMCF to assist federally inspected establishments to develop HACCP plans would serve as guides for the processes described earlier in this document. In order to clarify these concepts, some examples are included to explain the contrast in operations conducted under the HACCP system from those conducted under the traditional mode of industry operation. Since each HACCP system is developed by an individual establishment to fit with its process(es), the following examples are meant to serve only as illustrations, and are not intended to serve as prescriptive blueprints for a specific HACCP plan.

When developing a HACCP plan, all aspects of a food's production must be considered. The development of a HACCP plan begins with the identification of the product, its distribution, and the intended consumer of the product. A hazard analysis is conducted, and the plan is developed by identifying critical control points, monitoring procedures, critical limits, and the remainder of the seven principles discussed earlier in this document.

The HACCP system places the responsibility for production of a safe and unadulterated product with the industry. The HACCP approach allows the establishment to focus on the process as it is occurring. If contamination is occurring, it should be immediately identified, allowing for prompt corrective action as well as providing an opportunity to determine the cause and take action to prevent a future recurrence of the problem. In a non-HACCP approach, the establishment may not discover contamination until much later in the process, if at all, resulting in delays, the possibility of producing and distributing unsafe product, and difficulty in implementing preventive measures.

The following are illustrations of the application of existing generic models and how they can be used by an establishment.

The HACCP System for Beef Slaughter

For beef slaughtering establishments, a generic HACCP plan which reviews the processing steps of slaughter operations can provide general guidance for developing an establishment's specific plan. The goal of HACCP for slaughter operations is to prevent, eliminate, or reduce both the incidence and levels of microorganisms pathogenic to humans. While beef slaughter operations do not include a lethal treatment (e.g., thermal process) that ensures the elimination of pathogenic microorganisms, a number of the processing steps can be controlled to minimize microbiological hazards.

A beef slaughter establishment performing a hazard analysis of its operation may identify several hazards, particularly enteric pathogens, such as *Salmonella*. CCP's where *Salmonella* contamination might occur can be identified and then controlled by establishing critical limits, monitoring those limits at an appropriate frequency, and taking corrective actions when deviations occur. Recordkeeping and verification procedures would also be identified for these CCP's in the establishment's specific HACCP plan.

For example, the intestinal tracts of animals can harbor large populations of enteric pathogens, such as *Salmonella*, even though the animals themselves are asymptomatic. As the slaughtered animals are eviscerated (removal of the intestinal tract and other organs), there is potential for spreading the *Salmonella* from the intestinal tract to the carcass, operator, or equipment, if the intestines are accidentally cut. Therefore, evisceration would be considered a CCP in a HACCP plan for beef slaughter.

Critical limits for the evisceration CCP might be zero percent occurrence of the following defects for a single carcass: fecal material, ingesta, urine or abscesses. The establishment employee(s) working at evisceration would monitor by observing carcasses for contamination defects and would take corrective actions if the critical limits were exceeded. Corrective actions might include: immediate trimming of defects on carcasses, additional establishment employees added to the slaughter line, a reduction in line speed, sanitization of evisceration tools in 180°F water, and sanitization of contaminated clothing in 120°F water or appropriate sanitizer.

Records resulting from this CCP might include a random post-evisceration carcass examination log. Verification might consist of supervisory review of records and operations, and random examination of carcasses after evisceration using a sampling plan sufficient to assure process control.

In a non-HACCP approach, the establishment may discover contamination from evisceration much later in the process, causing delays before the contamination is removed and making implementation of preventive measures difficult.

Removing the hide from cattle is a major source of microbial contamination during the slaughtering process. Cattle entering the slaughter establishment carry with them microbial populations indicative of what occurred during the care and handling of the live animals. *Salmonella* and other types of bacteria can be spread during the skinning process through contact with hide, hands, and various pieces of equipment. Therefore, skinning would be a CCP in a beef slaughter HACCP plan.

Methods for control of contamination at skinning might include adequate training of the person doing the skinning to minimize contamination, including pulling the hide down and out from the carcass as opposed to upward and away; positive reinforcement through appropriate supervision; and proper cleaning and sanitization of equipment and carcass contact surfaces.

Monitoring at this CCP might include observation of the effectiveness of the skinning process for each carcass. Ways to ensure this is working would be to set critical limits. Critical limits for skinning might include less than or equal to 20 percent of carcasses with dressing defects.

If this critical limit is exceeded, corrective actions would be required. These could include: immediate trimming of defects on carcasses, additional establishment employees added to the slaughter line, and/or a reduction in line speed.

Records resulting from this CCP might include a random post-skinning carcass examination log. Verification might consist of a supervisory review of records, examination of random carcasses after skinning is complete using a sampling plan sufficient to assure process control, and reviewing control charts to confirm that sampling frequency is sufficient to detect 20 percent defect criteria. Additionally, baseline data might be established for expected bacterial numbers. Periodic

follow-up analyses and trend analysis might be performed to verify process control.

Other possible CCP's in beef slaughter are described in the ''Generic HACCP for Raw Beef'' (see Appendix).

The HACCP System for Poultry Slaughter

The current systems of postmortem inspection for poultry share elements of a HACCP system approach, such as critical limits, monitoring, corrective action plans, recordkeeping, verification tasks, critical limits or tolerance levels, monitoring tasks, corrective actions, and recordkeeping. However, these components are not arranged in the highly organized systematic manner that is evidenced in a HACCP system.

Major differences between a HACCP system and the present poultry slaughter systems are hazard identification and analysis, and the specific identification of critical control points which are not a part of current poultry slaughter systems. The progression to a HACCP system in poultry slaughter would cause some significant changes to emerge. These changes would include more industry involvement and responsibility for control of processes executed to produce an end product that is safe, wholesome, and unadulterated.

Under HACCP, the establishment would define processing steps where control can be exerted to effectively prevent, eliminate, or reduce food safety hazards. Because *Salmonella* is a significant microbial hazard in raw poultry, establishments would be expected to target measures that prevent contamination and control the growth of *Salmonella* throughout the slaughter process.

For example, under a HACCP system, the establishment may set criteria for maximum permissible levels of *Salmonella* in a flock presented for slaughter. CCP's for control of this enteric pathogen may include requiring that flock health records be reviewed, that the level of *Salmonella* on each flock brought for slaughter be monitored, and that corrective action be taken when appropriate levels are not met.

At evisceration, critical limits would be set for fecal or other intestinal contamination present on the carcass. Monitoring would be conducted at a set frequency, the results would be recorded after observing the carcasses, and corrective action would be taken if the limits were exceeded.

In addition, control of *Salmonella* may include targeting the chlorine level in the rinse water required for automatic evisceration equipment, the level of antimicrobial treatment in the chiller, and/or the temperature of the chill water. These would constitute CCP's identified by the establishment.

Critical limits would be set based on allowable levels and types of antimicrobials used, monitored by testing at appropriate frequency, and recorded in a log or other record.

Corrective action taken may include more frequent changes of chill water, better temperature control to preclude the growth of pathogens, or use of an alternate antimicrobial rinse.

Currently, some establishments rely on FSIS personnel to detect contamination by visual examination of the carcass or by using chiller water temperatures as an indicator of less than satisfactory conditions. This would occur as a result of end product examination. The HACCP approach requires the establishment to implement effective preventive measures.

Industry would follow a similar protocol for all points in the poultry slaughter process where a potential hazard can be prevented, eliminated, or reduced to an acceptable level. This demonstrates CCP's in an establishment-controlled HACCP system.

The HACCP System for Cooked Sausage

For the development of a HACCP plan, an establishment producing a cooked sausage must evaluate the entire manufacturing process. The focus of a HACCP plan on the prevention of food safety hazards requires defining where unsafe conditions can occur, setting target limits, and defining corrective action.

Cooked sausage is a broad category which includes frankfurters (hot dogs and wieners), vienna sausage, bologna, knockwurst, braunschweiger (liver sausage), and similar products. In this example, assume that the establishment produces bologna.

Because HACCP is a hazard prevention process control system, processing hazards must now be identified. The finished product—bologna—is a fully cooked product that can be consumed without further safety treatment (i.e., cooking).

Consequently, raw materials (meat and other ingredients) must be handled to reduce the opportunity for microbiological growth. CCP's requiring limits would include ensuring that incoming ingredients are adequately packaged to prevent contamination, and perishable ingredients are kept within temperature limits that assure their safety.

Cooking is considered a primary kill step in processed products where microbiological hazards can be controlled. Critical limits must be set by an establishment to assure that the product has been sufficiently heat treated to preclude the growth of pathogenic microorganisms. The manufacturer of a poultry bologna may set 160 °F as the critical limit for the internal temperature and test a set amount of product, recording the internal temperature, time the temperature was recorded, and the lot number and size.

If the product does not meet the critical limit set by the establishment, corrective action can be instituted that could include recooking the lot of product or chilling and reworking the lot into subsequent production.

The cooling process is another example of a CCP in the processing of a cooked sausage product. Improper chilling after the lethal heat treatment is applied can result in the growth of microorganisms (particularly vegetative spores) which may have survived the heating process. Improper chilling will permit the growth of these microbes and render the product unsafe.

The HACCP approach would ensure that an establishment targets chilling as a CCP, sets critical limits including time and temperature parameters (e.g., 5 hours to reach and maintain 40°F internally), monitors the temperature at frequent intervals, records the results, and takes appropriate corrective action if the critical limit is exceeded. Corrective action might include recooking the lot of product and recooling.

In addition to microbial hazards, physical and chemical hazards must be identified. The use of nitrite in cooked sausages serves two functions—color development and some protection against the outgrowth of anaerobic organisms. Under HACCP, an establishment would set a critical limit for nitrite in the product, monitor the formulation of each batch of product produced, record the exact amount of each ingredient used, and take appropriate corrective action if the limit were exceeded. Corrective action might include the addition of other ingredients, such as meat, to offset the addition of excess nitrite.

Therefore, it becomes the responsibility of the establishment under HACCP to identify CCP's, monitoring procedures, and corrective action that specifies what would happen to product that is or may be affected and what would happen to prevent the violation from recurring. Finally, all HACCP plans must identify the documentation that would occur to

verify that the process is operating appropriately.

D. Effective Dates

The proposed requirements for Sanitation SOP's, antimicrobial treatments, cooling standards for livestock carcasses, and microbial testing would be effective 90 days after the date of the final rule's publication in the **Federal Register**. This would afford those establishments not yet performing the proposed interventions the time to make necessary adjustments. Minimal preparation would be required to begin microbial testing. The requirement to begin tracking test results in accordance with the moving sums process-control procedures and reporting the results to FSIS would be effective 6 months after promulgation of the final rule. FSIS is proposing to hold establishments accountable for meeting the interim targets for pathogen reduction beginning 2 years after promulgation of the final rule.

The 6-month Hazard Analysis period would begin no less than 6 months before the HACCP phase-in date, as set forth for each of nine process categories and for small establishments, as provided in the proposed 9 CFR 326.7 and 381.607.

FSIS invites comment on these proposed effective dates.

III. Other Issues and Initiatives

A. Legal Authority

The Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) and the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) were enacted to protect the health and welfare of consumers by assuring that meat and poultry products distributed in commerce are ''wholesome, not adulterated, and properly marked, labeled and packaged'' (21 U.S.C. §§ 451 and 602). The term ''adulterated'' is defined in the Acts to include any meat or poultry product that is ''unsound, unhealthful, unwholesome, or otherwise unfit for human food'' (21 U.S.C. §§ 453 (g)(3) and 601(m)(3)). Meat and poultry products that bear or contain any poisonous or deleterious added substance which may render them injurious to health, and meat and poultry products that bear or contain inherent substances in sufficient quantity to ordinarily render them injurious to health are also ''adulterated'' within the meaning of the Acts (21 U.S.C. §§ 453(g)(1) and 601(m)(1)).

The term ''adulterated'' is also defined to include meat and poultry products that have been ''prepared, packed, or held under insanitary conditions whereby [they] may have become contaminated with filth, or whereby [they] may have been rendered injurious to health'' (21 U.S.C. §§ 453(g)(4) and 601(m)(4)). The FMIA specifically authorizes the Secretary to ''prescribe the rules and regulations of sanitation under which establishments shall be maintained'' and to refuse to allow meat or meat food products to be labeled, marked, stamped, or tagged as ''inspected and passed'' if the sanitary conditions of the establishment are such that the meat or meat food products are rendered adulterated (21 U.S.C. § 608). Similarly, the PPIA requires all official establishments to be operated ''in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary'' and authorizes the Secretary ''to refuse to render inspection to any establishment whose premises, facilities, or equipment, or the operation thereof, fail to meet the requirements of this section'' (21 U.S.C. § 456).

In addition to this specific authority, the Secretary has broad authority under both Acts to promulgate rules and regulations necessary to carry out the Acts (21 U.S.C. § 463, 621).

Based on these statutory provisions, FSIS is proposing that establishments take affirmative action, including adherence to sanitation standard operating procedures, the application of antimicrobial treatments and microbial testing, the adherence to cooling requirements for livestock carcasses, and the development and adherence to HACCP plans, to reduce the occurrence and levels of pathogenic bacteria on meat and poultry products and to protect the health and welfare of consumers. FSIS is also proposing, based on these statutory provisions, to establish interim targets for quantitative reductions in the incidence of contamination of meat and poultry with microbial pathogens. These actions to protect public health and improve the safety of meat and poultry products are authorized by the various provisions of the Acts referenced above.

B. Improving Food Safety at the Animal Production Stage

There is wide agreement that ensuring food safety requires taking steps throughout the continuum of production, slaughter, processing, distribution, and sale of livestock and poultry carcasses and meat and poultry products to prevent hazards and reduce the risk of foodborne illness. The U.S. food safety continuum begins on the farm. From there, animals are transported to markets and then to slaughtering establishments.

While FSIS is proposing significant enhancement in its regulatory oversight of FSIS-inspected slaughter and processing establishments, improving food safety at the animal production stage would require a different approach. Many producers recognize the need to play an active role in reducing microbiological and chemical hazards that originate on the farm. FSIS will work with producers and others to develop and foster implementation of food safety measures that can be taken on the farm and prior to the animals entering the slaughter facility to reduce the risk of harmful contamination of meat and poultry products. Within this context, the voluntary application of HACCP principles can be useful in establishing the CCP's within the farm management and live animal transportation arenas where pathogenic organisms can enter the food chain.

HACCP principles can be utilized also to structure voluntary national animal health programs that focus on risk reduction and producer incentives to reduce the prevalence of a given pathogen. Such voluntary programs can be built upon similar, successful food safety efforts presently in use. These include industry-sponsored quality assurance programs, such as the Milk and Dairy Beef Quality Assurance Program, a ten-point grassroots education effort by the National Milk Producers Federation and the American Veterinary Medical Association; pork and beef quality assurance programs developed by the National Pork Producers Council and the National Cattlemen's Association; the American Veal Association's quality assurance program; the GMP guidelines developed by the National Broiler Council and several quality assurance efforts by the United Egg Producers; the chemical-residue avoidance program of the National Turkey Federation; and the flock health-certification program of the American Sheep Industry Association. All these programs focus on actions that individual producers can take to improve the quality and safety of the products they market. These programs provide a foundation for building future on-farm food safety initiatives.

There may also be a link between on-farm control measures and the proposed mandatory implementation of HACCP in FSIS-inspected meat and poultry establishments. For example, establishments may determine that the external cleanliness or degree of external contamination of animals with pathogenic microorganisms at the time the animals enter the slaughter

establishment is a critical control point. This would require that the establishment and the producer work together to ensure that an appropriate critical limit has been met. This possible linkage between in-plant mandatory HACCP and the control practices of producers simply reflects the reality that improving the safety of meat and poultry products will require cooperative action across the entire food system from production on the farm all the way to the consumer. The expertise and commitment of the producer community will be critical to making real progress.

FSIS invites comment on the role it can best play to improve food safety at the animal production stage. Because FSIS resources in this area are limited, the private sector must continue and perhaps expand its efforts and initiatives. One role FSIS expects to play is as a facilitator of research and other activities designed to define problems and opportunities for improvement and develop animal production technologies and practices that can improve food safety. FSIS intends to work closely with academic researchers, other government agencies, producer groups, and consumer organizations to help shape an appropriate research agenda and devise effective on-farm food safety strategies.

FSIS also intends to work closely and cooperatively with producers and with State health and agricultural officials when outbreaks of foodborne illness necessitate investigations to trace a safety problem to its origins which may in some cases be at the animal production stage. Such investigations are a problemsolving tool intended to assist public health authorities in controlling an ongoing food safety problem and finding means to prevent or reduce the likelihood of occurrence of the problem in the future. Traceback investigations are resource-intensive and difficult to conduct. They require cooperation among government agencies at all levels and with the animal production and processing industries. FSIS invites comment on the appropriate role of traceback investigations and how they can best be conducted and used to improve food safety.

C. Transportation, Distribution, Storage, Retail

Just as food safety hazards can arise before animals enter the slaughterhouse so too can they arise after meat and poultry products leave FSIS-inspected slaughter and processing establishments. The transporter, the wholesaler, the retailer, and the food service industry are important links in the chain of responsibility for food safety that extends from the farm to the consumer. FSIS has historically focused on the manufacturing of meat and poultry products, but the Agency's public health mandate requires that it also work with the animal production, transportation, distribution, and retail sectors to implement effective prevention strategies and ensure that the whole system is working effectively to prevent food safety problems.

FSIS and FDA share authority and responsibility for overseeing the safety of meat and poultry products after they leave FSIS-inspected facilities. In accord with the Administration's National Performance Review, FSIS and FDA have agreed to work together to ensure effective oversight and the adoption of preventive approaches through the chain of transportation, distribution, storage, and retail.

FSIS exercises regulatory oversight of meat and poultry products in transportation, storage, and distribution channels through the activities of about 130 compliance officers who conduct a nationwide monitoring program to prevent adulterated or misbranded product from reaching consumers. FDA also conducts regulatory activities in this sector. In addition to monitoring retail food safety programs at the State level, FDA provides technical assistance to States in the form of a uniform code (the *Food Code* discussed below) that prescribes appropriate food handling practices in distribution and retail channels.

FSIS and FDA will review their respective programs to determine how they can, considering all of the resources being devoted to this sector, reconfigure the program or initiate activities to increase program effectiveness. Two specific areas of review will be transportation of product in commerce and handling and preparation of food products by retail stores, restaurants, and institutions.

In the area of transportation, FSIS is currently working with FDA on the development of guidelines for conveyances used to transport food products. FSIS and FDA have agreed to:

- Ask a group of experts to provide systematic information on the hazards and controls that currently exist;
- Develop practical standards of performance for establishments and carriers with respect to the transport of food;
- Develop a list of Good Manufacturing Practices and options for encouraging their use;
- Initiate joint rulemaking to establish appropriate standards to ensure the safety of meat and poultry products and other foods during transport;
- Work with the Department of Transportation to implement the National Food Safety Transportation Act, and investigate whether additional authority is needed to carry out the shared food safety mission of FDA and FSIS.

In the area of retail distribution, FSIS has worked closely with FDA in the recent updating of the Food Code, a set of model ordinances that serve as a guide for State and local authorities who have primary responsibility for the regulation of retail stores and restaurants. FSIS and FDA will continue to work on making the code comprehensive, focusing on areas of greatest concern, and using existing FDA mechanisms such as seminars, workshops, and evaluations for getting the word out in a timely manner on important changes and assuring good understanding of the practices involved. FSIS and FDA will collaborate in presenting issues to the Conference for Food Protection and in responding to the Conference's recommendations, on which the States vote. In addition, the two agencies will work together to facilitate State audits, and to provide assistance for whatever changes the audit results indicate.

FSIS and FDA will also work together to encourage State adoption of the *Food Code* as a means to ensure that consistent, science-based food safety standards are being observed at the retail level across the country.

D. Health-Based Standards for Pathogenic Microorganisms

Overview

As explained elsewhere in this document, the FSIS food safety regulatory strategy rests on articulating what constitutes an acceptable level of food safety performance by meat and poultry establishments and holding establishments accountable for achieving that level of performance. The proposed HACCP regulations will provide the framework for adoption by all meat and poultry establishments of the science-based preventive controls that will be necessary to achieve the food safety objectives established by FSIS.

As an initial step toward articulating an acceptable level of food safety performance and reducing the frequency and degree of contamination of meat and poultry products with pathogenic microorganisms, FSIS is proposing to require reductions in the incidence of one pathogenic microorganism of significant public health concern,

Salmonella, based on what is achievable in the near term with available science and technology. FSIS may in the future adjust the interim targets for *Salmonella* downward, as experience warrants, and may consider adopting similar technology-based interim targets for other pathogens.

As explained earlier in this document, FSIS also intends to pursue over the long term development of science-based food safety performance standards that are based on what is necessary and appropriate to protect public health. This is the approach typically taken in the regulation of chemical residues in food: tolerances are established that limit the amount of residue that can be lawfully present based on an assessment of what limit is necessary to ensure the safety of the food. For certain cooked, ready-to-eat products, and more recently in the case of *E. coli* 0157:H7 in raw ground beef, FSIS has determined that pathogens at any level pose a safety concern and legally adulterate the product, in effect setting a zero tolerance for such pathogens.

Other than *E. coli* 0157:H7 in raw ground beef, a potential hazard that survives traditional cooking practices followed by many people, FSIS has not taken this approach with pathogenic microorganisms contaminating raw meat and poultry products. FSIS has relied in part on the fact that proper and generally accepted cooking practices kill most pathogens present in most raw products. It is also believed that for some important pathogens, such as *Salmonella, Staphylococcus aureus* and *Bacillus cereus*, some minimum number of organisms may be required to pose a significant threat of illness, although there is much scientific uncertainty in this area and susceptibility to illness varies among individuals.

The task of establishing science and public-health based food safety performance standards for meat and poultry products, such as by identifying levels of specific pathogens that pose a threat to public health and requiring that those levels not be exceeded, raises difficult scientific and public health policy issues. These include determining the nature of the hazard posed by particular pathogens and the actual threat to health posed under various conditions of exposure to the pathogen—an inquiry commonly referred to as risk assessment. In setting such standards, it also must be determined how protective the standard is to be: how strong must the assurance of safety be? Is any degree of risk acceptable? How can potential risks be managed by quantitative limits, labeling or some combination of measures? Addressing these public health policy issues is sometimes referred to as risk management.

FSIS invites public comment on the utility of health-based food safety performance standards and the issues involved in developing them. FSIS also intends to hold one or more public meetings to explore this topic with interested persons and experts in the industry, scientific, consumer and public health communities. Details on the time, place, and agenda for such meetings will be published in a future issue of the **Federal Register**. While the public health policy issues in this area are difficult and important, it is necessary first to consider the scientific basis for setting health-based food safety performance standards. The following paragraphs describe the current state of knowledge in this area and some of the scientific issues that need to be addressed.

Quantitative Risk Assessment for Microbial Pathogens

Integral to development of public health-based food safety performance standards is an understanding of the relationship between bacterial levels and the incidence of disease. The likelihood that an exposure to a foodborne pathogen will produce a disease response in an individual is dependent on the pathogenicity of the microorganism, the level of exposure (i.e., number of microorganisms ingested), and the susceptibility of the host. Qualitative and quantitative consideration of these factors is the basis for conducting a microbial risk assessment.

Pathogenicity describes the overall disease-causing capability of a microorganism. The inherent potential for a microorganism to cause disease is associated with one or more genetic characteristics (i.e., virulence factors). The virulence of a species is reflected in the levels of the microorganism that are needed to colonize a host and produce an infection or toxigenic response, as well as the severity (i.e., medical consequences) of the disease. However, pathogens must always be considered in the context of their host, since disease processes are dependent on host/pathogen interactions. In any population, individuals will have a varied response to any specific pathogen. This includes both the levels of the pathogen needed to elicit an infection or morbidity, and the extent and duration of symptoms. Typically, there will be a distribution of susceptibilities as a function of the levels of ingested pathogen.

This distribution of the host and pathogen characteristics means that the potential for infection must be treated as a probability function. This approach is replacing the older concept of minimum infectious dose, which fails to take into account the distribution of susceptibility within the host population. As the number of pathogen cells to which the host population is exposed increases, there is a corresponding increase in the probability of infection among the population.

The amount of data on the quantitative dose-response relations for human and various foodborne pathogens is severely limited. However, available data do allow estimation of infection rates for many foodborne pathogens. In many instances this may be sufficient since, barring exceptional pathogenic resistance or host susceptibility, the key data for a microbial risk assessment in foods are estimates of exposure (i.e., the numbers of pathogens ingested by consumers) and their correlation with infection rates.

A key limitation on the application of risk assessment techniques to microbial food safety issues has been that, unlike most chemical toxins, the levels of bacteria in food are not constant. They can change drastically as the result of growth or inactivation. The ability to run risk assessment scenarios to study the potential impact of changing food processing or food preparation protocols is dependent on acquiring a reasonable estimate of the levels of a pathogen consumers are ingesting. The ability to estimate exposure is, in turn, dependent on being able to estimate (1) The probability that the pathogen is present in the food ingredients, (2) the initial levels of the pathogen that can be expected if the microorganism is present, and (3) how these levels are likely to change as a result of operations associated with the processing, preparation, and storage of the food. While there are still methodological limitations, recent advances in predictive microbiology and the systematic collection of baseline data on the presence of pathogenic bacteria in foods have begun to allow the first quantitative microbial risk assessments.

In the case of some significant foodborne illness sources, such as contamination of raw poultry with *Salmonella* and *Campylobacter*, the illness is more often caused not by direct consumption of the contaminated food but by cross-contamination of other foods during handling and preparation. FSIS is not aware of research having been done to correlate levels of specific

pathogens in raw meat or poultry with the risk of cross-contamination and consequent illness. Whether experimentally derived or acquired through correlation of community disease rates and pathogen levels in meat or poultry, FSIS would be interested in reviewing any available data. At the same time, recognizing the key nature of such data, FSIS is committed to working with the CDC and the research community to obtain the necessary information.

Finally, quantitative risk assessment for pathogenic microorganisms is complicated by the wide variability in susceptibility to particular pathogens among individuals and groups of individuals in the population. It is well known, for example, that the young and the elderly are at significantly greater risk of serious illness or death from consumption of *E. coli* 0157:H7 than the general population. Any person with a weakened or compromised immune system, whether due to age or illness, is generally more vulnerable to foodborne illness associated with pathogenic microorganisms. Thus, in developing the scientific basis for risk assessment, attention must be paid to these subpopulations so that any resulting health-based standard will be adequately protective of the population as a whole.

Future Activities

FSIS intends to work closely with the Centers for Disease Control and Prevention, the Food and Drug Administration, other public health agencies, academic scientists, and the industry and consumer communities to develop the scientific basis for microbial risk assessment and the creation of health-based performance standards for pathogenic microorganisms. FSIS recognizes that the scientific issues are difficult and that it may not be possible in the near term to establish health-based standards for all pathogens. It is important to begin this effort, however, because, as progress is made in the near term toward pathogen reduction on the basis of available technology, it will be increasingly important to know what constitutes an acceptable level of food safety performance from a public health perspective. Health-based performance standards can provide an incentive for further improvement and progress in reducing pathogenic microorganisms and an indication of the point beyond which further reduction would be unlikely to yield a public health gain.

FSIS will seek to stimulate—and to a limited extent conduct and support—the scientific research needed to develop quantitative risk assessment methods and databases for pathogenic microorganisms. This will likely include laboratory research, in-plant studies and community-based epidemiological studies to evaluate health outcome in meat and poultry inspection. FSIS intends to use the public meetings mentioned above to canvass the current state of knowledge in this area and encourage development of a coherent research agenda that can contribute to progress in this important area.

E. FSIS Technology Strategy

Overview

FSIS has a longstanding interest in the technologies used in meat and poultry establishments. The facilities, equipment, and processes used during slaughter and processing of meat and poultry can significantly affect the safety, quality and wholesomeness of the finished product. The safety of the product can be affected adversely by the wrong technology, such as equipment whose food contact surfaces cannot be adequately cleaned, or by misuse of a technology, such as a chemical sanitizer or preservative that is used above established safe limits.

There are also many technologies that can be used in meat and poultry establishments to help protect product from physical, chemical, and biological, especially microbiological, hazards. These include laboratory and in-plant methods to test for chemicals, animal drugs and bacteria; technologies for preventing harmful contamination by pathogenic microorganisms; chemicals or physical treatments that can be applied to carcasses to reduce pathogens; and equipment to verify pathology diagnoses.

FSIS currently regulates virtually all substances, processes, and pieces of equipment found in meat and poultry establishments that might affect the safety, quality, or wholesomeness of the product, through either prior approval on a plant-by-plant basis or publication of generic approvals or lists of approved items. The principle objectives FSIS pursues with these mechanisms are to ensure that the technology does what it is claimed to do (especially if the claim is safety related) but does not jeopardize the safety or wholesomeness of the product, cause or contribute to economic adulteration, interfere with FSIS inspection, or jeopardize the safety of inspectors.

Recently, members of the regulated industry have complained that the Agency's control mechanisms, especially its prior approval processes, stifle innovation and may retard technological progress that can improve food safety in such important areas as pathogen reduction. At the same time, representatives of consumer groups have expressed concern that technologies claimed to be effective for pathogen reduction and other important food safety purposes be proven effective for that purpose and that the scientific processes used by FSIS to evaluate technologies be more open to public scrutiny and participation.

FSIS believes that the development and proper use of technology can contribute significantly to improving the safety of the food supply, especially with regard to reducing the threat posed by pathogenic microorganisms; and can, in general, improve the Agency's ability to carry out its mission. The FSIS food safety strategy depends heavily on establishing food safety objectives for the meat and poultry industry, which in turn provide an incentive for industry to innovate to meet those objectives. To make this strategy work, FSIS must not be an obstacle to beneficial innovation.

Therefore, FSIS is reviewing its current policies and procedures governing review and approval of in-plant technologies with the intention of simplifying them to the maximum extent possible, while ensuring that important safety and efficacy issues are considered. FSIS invites comment on its technology strategy, including the issues and activities outlined below. FSIS also intends to convene one or more public meetings to gain further input on how it can improve its role in fostering and overseeing the implementation of new technologies to improve the safety of meat and poultry products. Some of the Agency's current perspectives and activities in the area of technology development and evaluation are outlined below.

Current Perspectives and Activities

As a general rule, the development of technologies required to produce safe and wholesome products is a responsibility of the meat and poultry industry and allied enterprises, such as equipment designers and manufacturers, pharmaceutical companies, analytical laboratories, manufacturers of non-food compounds, and many others. Innovative technologies are continually developed by these entities to enhance productivity and profitability in the meat and poultry industry. FSIS believes that industry innovation can also be directed to improving food safety if the right incentives exist. FSIS intends as part of its long-term food safety strategy to increase the incentive for such innovation by establishing

public health-driven targets, guidelines, or standards that establishments will be held accountable for meeting. This should have its greatest impact in slaughter establishments, where such targets, guidelines, or standards do not generally exist today.

FSIS will focus its own limited technology development efforts on tools that can assist the Agency in detecting and evaluating food safety hazards or addressing other issues within its statutory responsibility, such as economic adulteration. These efforts have traditionally included, and will continue to include, the development of sensitive and reliable analytical methods and diagnostics that can assist the Agency in verifying the safety of meat and poultry products and detecting product characteristics of regulatory interest. FSIS will also continue its efforts to develop tools that it can use to advance its food safety mission but that require long-term commitment to develop, such as various computer models on pathogen behavior. In these cases, the Agency has (1) carried out its own technology development efforts, as it did in developing quick tests for antibiotics and species identification; (2) secured the assistance of the Agricultural Research Service and Cooperative State Research Service, as it has done with computer modeling of pathogen growth under various times and temperatures; and (3) occasionally, supported specific work by academic institutions or other private entities through use of competitive bidding processes, as it did recently by awarding more than $700,000 in contracts for development of methods to detect pathogenic microorganisms.

The resources available to FSIS for such technology development activities are very limited. Moreover, FSIS has found that there is often considerable interest within the regulated industry in using technologies that were originally developed by FSIS. FSIS intends to explore mechanisms for stimulating private sector investment in analytical methods and other technologies that can assist the Agency in its regulatory role but that also can assist the industry in carrying out its food safety responsibilities.

FSIS believes that its primary role with respect to new in-plant technologies developed by industry should be to ensure that the technologies do not interfere with inspection, threaten the safety of the product, or violate other statutory standards, such as those concerning economic adulteration.

In some circumstances, the FSIS evaluation of a new technology may need to consider the efficacy of the technology, that is, its success in accomplishing its intended objective. For example, if FSIS has a regulatory requirement for the use of an antibacterial treatment, as is proposed elsewhere in this document, the Agency will take an evaluative interest in whether a specific treatment in fact has the intended and required effect. In addition, if a company intends to make a marketing claim for a process or technology used in an establishment—such as a claim that its product is ''pathogen free''—FSIS will require a demonstration that the claim is valid.

On the other hand, in circumstances where industry interest in the technology is not based on required or claimed health and safety effects, but on a productivity concern, FSIS interest will be limited to ensuring that relevant safety questions have been addressed.

When FSIS makes significant decisions about the safety or effectiveness of an in-plant technology, it must ensure that its decisions are scientifically sound and open to appropriate public scrutiny and participation. An example of how this can be achieved is the approach taken in an earlier section of this document to inviting public comment on the possible antimicrobial treatments that might satisfy the proposed requirement that all meat and poultry establishments adopt at least one antimicrobial treatment. FSIS invites comment on this approach and other means for ensuring that its scientific decisions are sound and open to public scrutiny.

During the past several years, staffs in the Agency have begun efforts that would permit technological change to proceed more readily from the development to the implementation stage. The Facilities, Equipment and Sanitation Division has explained many of the principles and criteria that it uses to make decisions in publicly available documents so that they can be readily understood and used by companies as they plan changes in their physical plants. The Microbiology Division has provided public notice about the circumstances under which it will formally evaluate analytical methods that may be useful in the FSIS program, and it has negotiated a Memorandum of Understanding with the AOAC Research Institute that will permit manufacturers of test kits designed for use by the industry to have their technologies evaluated for that purpose. The Processed Products Inspection Division has developed guidelines to be used in preparing various required QC programs. The Slaughter Inspection Standards and Procedures Division has developed and made available protocol guidelines so that companies that want to conduct in-plant demonstrations of antimicrobial treatments will know what is necessary to secure Agency approval.

Providing clear guidance of this kind assists companies in meeting the Agency's requirements and will continue to be an important part of FSIS's effort to improve its technology review function. As outlined below, however, FSIS intends to take a number of additional steps to help foster development, appropriate review, and prompt implementation of beneficial new technologies, especially those that can help improve the safety of meat and poultry products.

Future Agency Activities

As already noted, FSIS is reviewing all of its existing systems of prior approval or other procedural requirements that are now in place regarding the development and implementation of technologies in meat and poultry establishments. The Agency intends to eliminate, streamline, or otherwise modify its systems and procedures, as appropriate, to ensure that its legitimate oversight obligations are met without unduly delaying the introduction of beneficial new technologies or imposing unnecessary burdens on establishments seeking to adopt such technologies.

One approach FSIS is considering is a simplified single-stop approval mechanism for industry-wide application of proven pathogen reduction technologies, once necessary laboratory and in-plant trials have been completed and the data have been evaluated. The generic approvals FSIS recently granted for use of hot water and organic acids in conjunction with the final carcass wash in beef slaughter establishments could provide a workable model for expediting the adoption of pathogen-reducing technological developments. The Agency's scientific evaluation would be for the purpose of ensuring that efficacy is demonstrated, that conditions of use are specified so the technology can be widely replicated, and that verification techniques are available. Once this scientific evaluation has been completed on a generic basis, approval for industry-wide use without further constraints, such as plant-by-plant review, could be granted by the Administrator or his/her designee. FSIS invites comment on this approach, including what public process would be appropriate in making such decisions.

FSIS is also establishing a single point of contact in the Agency regarding technology development and implementation. This will be the newly constituted office of technology development in the Science and Technology Program. This office will serve as the initial point of contact for all inquiries about technology development, and it will help coordinate evaluations that involve multiple divisions in the Agency so that responses to inquiries will be timely and complete.

This office will also coordinate development of, and make available to interested parties, a single guideline for experimental protocols to be submitted to the Agency prior to commencing an in-plant study of a new technology. Some new technologies need to be evaluated in in-plant trials to determine their safety and effectiveness before they can be appropriately evaluated by FSIS. The Agency does not intend to impede those trials, but it must be assured that they produce data that will be adequate to address the Agency's concerns. Thus, one important element of the guideline will be a description of the information that must be submitted to satisfy the Agency's basic safety concerns. For those circumstances in which the Agency will be evaluating the efficacy of a technology, the guideline will provide detailed information about the Agency's expectations for data offered to demonstrate efficacy. This information will address such areas as the quality of the experimental design, the necessary quantity and quality of data, the plan for data analysis, and other relevant elements.

Finally, FSIS intends to interact publicly with the regulated industry and all interested parties to foster the development of beneficial new food safety technologies and to improve how the Agency plays its role in this critical area. In areas where FSIS is engaged in technology development of its own to advance its regulatory objectives, the Agency intends to identify research that is needed to support its efforts. FSIS is also interested in learning more about the opportunities that exist for improving food safety through the adoption by establishments of scientifically sound processes and technologies in both slaughter and processing operations, and the Agency seeks public input on its effort to improve its systems for reviewing and approving new technologies. As a first step, FSIS intends to hold a public meeting on these topics during the comment period on the regulations proposed elsewhere in this document. Details on the time, place and agenda for this meeting will be published in a future issue of the **Federal Register**.

F. FSIS Inspectional Roles

The current FSIS program, as described in Part I of this document, is fundamentally an inspection program. It is a program designed to ensure through inspection that proper sanitary practices are observed, that organoleptically detectable defects, including diseased and contaminated carcasses, are excluded from the food supply, and that other requirements and standards related to safety, economic adulteration, and misbranding are met.

The long-term FSIS food safety strategy and the HACCP proposal set forth in this document will bring about substantial change in industry practice and in the FSIS program, as the Agency clarifies and reinforces the industry's responsibility for producing safe food, prepares to play its oversight role to ensure companies are implementing HACCP properly, and works to ensure that all participants in the food system—producers, processors, distributors and retailers—are meeting their food safety responsibilities.

With these changes, inspection of products and practices will remain central to the FSIS program. HACCP verification will necessarily expand the roles in-plant inspectors will be called upon to play, and HACCP will enhance the contribution in-plant inspection can make to ensuring the safety of food. In addition, the need to address food safety across the continuum from the farm to the consumer, as discussed in the preceding sections of this document, raises the question of the role FSIS inspectional oversight should play outside of slaughter and processing establishments.

Although the demands that will be placed on the FSIS inspection force by HACCP and other elements of the Agency's food safety strategy will develop over the next two to four years, it is important that FSIS begin considering now the future roles of the FSIS inspection program and how FSIS can maximize the contribution its inspectors make to ensuring the safety of the food supply. One of the Agency's most important challenges and obligations is, by means of training and a clear definition of roles and responsibilities, to prepare its workforce to meet the demands of the future.

In the course of developing the food safety strategy and regulatory proposals set forth in this document, FSIS has consulted with the National Joint Council (NJC) of Food Inspection Locals of the American Federation of Government Employees, which represents the Agency's food inspectors, as well as organizations representing the Agency's veterinarians (National Association of Federal Veterinarians (NAFV)) and technical and supervisory personnel (Association of Technical and Supervisory Personnel (ATSP)). The Agency will continue this consultation throughout the pathogen reduction and HACCP rulemaking process. FSIS also intends to work closely with the bargaining unit and the employee organizations in formulating a plan for the optimal utilization of the Agency's inspectional workforce, and FSIS will comply fully with its obligations under the Basic Agreement with the NJC to bargain on matters that impact inspectors.

The Agency's employees and their representatives are strongly committed to ensuring the safety of the food supply and building the best possible food safety program. They have a critically important expertise and perspective that must be brought to bear in developing optimal roles and responsibilities for FSIS employees.

Many of the current roles of FSIS inspectors are controlled by the statutory mandates for: (1) Carcass-by-carcass inspection in slaughter establishments; (2) continuous FSIS inspectional presence in all processing establishments; and (3) inspectional responsibilities for non-safety wholesomeness and economic adulteration. FSIS is committed to carrying out these existing mandates. Moreover, changes in FSIS inspectional roles will be constrained by the level of resources available to support the inspection program. Nevertheless, some of the inspectional issues FSIS expects to be addressing are outlined below.

FSIS recognizes that food safety begins at the original point of production of the food animal—the farm—and can be affected at every step along the way, including each step of animal production and transportation leading to delivery of the animal to the slaughterhouse. Many in the agricultural producer community have recognized the potential for applying quality assurance principles, including HACCP, on the farm to prevent the introduction of potential food safety hazards at their source. Although the Agency welcomes this initiative, FSIS does not currently have and does not anticipate on-farm inspectional authority.

As discussed in Part I, the first point of FSIS inspection is the antemortem inspection that occurs just before animals enter the slaughter process. It is appropriate to consider whether FSIS should broaden its antemortem inspectional oversight of conditions

under which animals are held in the period immediately before slaughter within its current authority. This is a period during which the health of the animal and its external cleanliness and degree of external microbial contamination can be affected in a way that may adversely affect food safety.

The FSIS in-plant inspectional role will certainly be affected by adoption and implementation of HACCP. As explained above in the portion of this preamble relating to the HACCP proposal, FSIS inspectors will be playing a verification role to ensure that appropriate HACCP plans are in place, are being implemented properly by the establishment, and are achieving the desired food safety results. This role will require increased activity by FSIS inspectors in the areas of records review, visual process verification, and product sampling. FSIS inspectors will, in some cases, have to develop new skills to carry out these activities within the HACCP framework. FSIS will be focusing on the specific additional tasks FSIS inspectors should be performing under HACCP and the training and skills that will be required.

FSIS is considering, in concert with FDA, the need for additional standards and Federal oversight to ensure that food is handled safely during transportation and distribution from processing establishments to the retail level. In the case of meat and poultry products, it is critical that products be shipped and stored in sanitary conditions and, in many cases, under refrigeration. If Federal standards are developed in this area, FSIS will have to consider what the role of Federal inspectors should be in ensuring such standards are met. No Federal agency would have the inspectional resources to inspect on a regular basis all of the hundreds of thousands of trucks, trains, vessels, planes, and storage/distribution facilities in the United States. FSIS will be considering whether there is an appropriate role for a targeted approach to inspection or random surveillance inspection, perhaps in collaboration with State and local food safety authorities, that would help ensure that safe practices are being observed at these critical stages of the food safety continuum. FSIS is interested in determining whether technologies, such as recording thermometers or temperature indicators on refrigerated trucks, could be adopted to enhance the roles of some relatively limited, periodic inspectional oversight and enable FSIS inspectors to work effectively in this area with inspectors from FDA and from counterpart agencies at the State and local levels.

At the retail level, FSIS intends to work closely with FDA and State and local officials and will continue to rely primarily on State and local authorities for inspectional coverage of restaurants, grocery stores and other conventional retail outlets. FSIS will be exploring how FSIS inspectors and field compliance officers can better collaborate with State and local food safety inspectors and other officials.

The FSIS inspection program for imported products relies on review of foreign inspection systems and exporting establishments to ensure that their approaches to food safety are equal to the U.S. approach, coupled with limited reinspection of incoming product at the U.S. border by FSIS inspectors. FSIS currently reinspects approximately 10 percent of import shipments, relying largely on organoleptic inspection techniques. Foreign establishments exporting to the United States will be required to adopt the pathogen reduction measures and HACCP requirements FSIS imposes on domestic establishments pursuant to this rulemaking. As HACCP develops, FSIS will be considering what effect adoption of HACCP should have on the nature and frequency of import inspection, including whether microbial testing should be incorporated, whether the periodic inspections FSIS currently conducts of foreign establishments should change, and how FSIS could best gain assurance on a continuing basis that establishments exporting to the United States are properly implementing appropriate HACCP plans.

Finally, some groups advocate amendment of the FMIA and PPIA to alter or repeal the current requirements for carcass-by-carcass and continuous inspection in meat and poultry establishments. This is necessarily an issue Congress would have to decide. As discussed in Part I of this document, carcass-by-carcass and continuous inspection play an important role in ensuring sanitation compliance is maintained, excluding diseased animals from the food supply, and detecting and removing other defects, such as fecal contamination, which are directly related to food safety. FSIS believes that, under any model of inspection, these objectives must continue to be met if food safety is to be ensured and the legitimate expectations of the public concerning the safety and quality of the food supply are to be satisfied.

Some propose that, with or without any statutory change in the carcass-by-carcass and continuous inspection mandates, establishments take more initiative in these areas. FSIS must consider how FSIS inspectors could verify with an acceptable degree of confidence that functions currently performed by a Federal inspector are being performed consistently, with the same rigor and effectiveness, by establishment employees. If establishment employees take on such functions currently performed by FSIS employees, consideration will have to be given as to whether ''whistleblower'' protection, which would shield them from retaliation of any kind for reporting problems, should be extended to them.

In general, under its proposed pathogen reduction and HACCP regulatory initiatives, FSIS will be considering what new inspectional tools and techniques FSIS should adopt to oversee the safety of meat and poultry products in a regulatory environment where greater responsibility for safety is being placed on establishments and their employees.

FSIS invites comment on these issues and on all aspects of how FSIS can best make use of its inspectional resources to improve the safety of meat and poultry products, both within currently inspected establishments and throughout the continuum from the farm to the consumer.

IV. Economic Impact Analysis and Executive Orders

A. Executive Order 12866

This proposed rule has been determined to be economically significant and was reviewed by OMB under Executive Order 12866.

Summary: Preliminary Regulatory Impact Assessment HACCP and Related Near-Term Initiatives Produce Net Benefit to Society

FSIS has prepared a Preliminary Regulatory Impact Assessment (PRIA) that evaluates the costs and benefits of a mandatory HACCP regulatory program and related near-term initiatives for all meat and poultry establishments under inspection. The PRIA concludes that mandating HACCP systems would result in net benefits that far exceed industry implementation and operation costs. Mandatory HACCP Program implementation at a cost of $2 billion over 20 years is projected to produce a direct reduction in foodborne illness with public health benefits estimated at $6–24 billion over 20 years.

The proposed near-term requirements, which would be incorporated into HACCP, would target pathogen reduction on carcasses and raw product, currently the products with the least systematically controlled hazards. The

benefits are calculated for the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli* 0157:H7, *Salmonella* and one environmental pathogen *Listeria monocytogenes*. The minimization of risk from these pathogens which can contaminate meat and poultry during slaughter and processing would produce a 90 percent reduction in the foodborne illness attributed to these pathogenic microorganisms. Ten percent of contamination occurs after the product leaves the manufacturing sector.

Industry costs to develop, implement, and operate HACCP processing control systems are estimated to total $2 billion over 20 years. The proposed regulation would redistribute costs in a manner more acceptable to societal values which have always given priority to eliminating controllable diseases. Establishments that now have good processing controls would have relatively few implementation costs, while establishments that have little or no process control would need to spend more for compliance.

Market Failure Justifies Regulation of Pathogens

Since all raw meat and poultry products contain microorganisms which may be pathogens, raw food unavoidably entails some risk to consumers of pathogen exposure and foodborne illness. The presence and level of this risk cannot be determined by a consumer since pathogens are not visible to the naked eye. The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by pathogenic microorganisms. Consumers often cannot trace a transitory illness to any particular food or even be certain it was caused by food. Thus, food retailers and restaurateurs are generally not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable either.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors have little incentive to incur extra costs for more than minimal pathogen controls. The widespread lack of information about pathogen sources means that businesses at every level from farm to final sale can market unsafe products and not suffer legal consequences or a reduced demand for their product.

The science and technology required to reduce meat and poultry pathogens is well established, readily available, and commercially practical. FSIS has concluded that the lack of consumer information about meat and poultry product safety and the absence of adequate incentives for industry to provide more than minimal levels of processing safety represents a market failure requiring Federal regulatory intervention. The present combination of market regulation and industry self-policing has not resolved increasingly apparent problems with meat and poultry pathogens. Documented cases of foodborne illness each year, some of which have resulted in death, represent a public health risk that FSIS has determined to be unacceptable. A Federal regulatory program that reaches every level of meat and poultry processing for commerce is the only means available to society for lowering foodborne pathogen risks to an acceptable level. FSIS further concludes that a mandatory HACCP regulatory program is the only means to attain this goal.

Alternatives

Process Control Regulatory Strategy

FSIS has determined that effective process control is needed throughout the meat and poultry industry in order to minimize pathogen contamination of food products and lower the risk of subsequent foodborne illness.

The process control regulatory strategy was evaluated using five factors for effectiveness:

1. Controls production safety hazards;
2. Reduces foodborne illness;
3. Makes inspection more effective;
4. Increases consumer confidence; and
5. Provides the opportunity for increased productivity.

Using these factors, FSIS has determined that mandatory HACCP provides the greatest effectiveness.

FSIS examined six other process control approaches before determining that mandatory HACCP was the most effective means for industry to eliminate pathogens in meat and poultry:

1. Status quo;
2. Intensify present inspection;
3. Voluntary HACCP regulatory program;
4. Mandatory HACCP regulation with exemption for very small establishments;
5. Mandatory HACCP regulation only for ready-to-eat products; and
6. Modified HACCP—negative records only.

Each of these alternatives was assessed using the five effectiveness factors for process control presented in the previous section. None was determined to meet all five criteria; each was found to be flawed in meeting one or more of the target factors.

The full text of the Preliminary Regulatory Impact Assessment is published as a supplement to this document.

B. Executive Order 12778

This proposed rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the FMIA and PPIA from imposing any requirements with respect to federally inspected premises and facilities, and operations of such establishments, that are in addition to, or different from, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements on State-inspected products and establishments that are at least equal to those required under the FMIA and the PPIA. These States may, however, impose more stringent requirements on such State-inspected products and establishments.

C. Effect on Small Entities

The Administrator, Food Safety and Inspection Service, has determined that this proposed rule will have a significant economic impact on a substantial number of small entities. For purposes of this proposal, a small entity is defined as an establishment with a sales volume of meat and/or poultry products of no more than $2.5 million per year. Based on this criterion, as of November 1994, there are 6,827 small slaughter and/or processing establishments that would be affected by this proposed rule. This analysis assumes that 5 percent of these small establishments or 341 establishments are currently operating under all the proposed requirements. Therefore, for these 341 establishments, this proposed rule would impose no additional costs.

For the remaining 6,486 small establishments, costs would be incurred as follows:

Near-Term Requirements

1. Sanitation Standard Operating Procedures

Establishments would be required to develop a written plan addressing the required operating procedures, monitor

the plan, record the results of monitoring, and store any records generated under the operating procedures. Establishments would also be required to train one or more individuals to carry out the operating procedures. Costs for this activity are estimated at $50.4 million.

2. Use of an Antimicrobial Treatment

Establishments would be required to use an antimicrobial treatment on all meat and poultry carcasses. Of the 1,923 small slaughter establishments, it is estimated that approximately 70 percent now apply an antimicrobial treatment to meat and/or poultry carcasses. Therefore, for these establishments, no additional costs should be incurred. For those establishments that do not now use an antimicrobial treatment, costs are estimated at $2.7 million.

3. Time/Temperature Requirements

Establishments would be required to provide written plans for complying with the proposed time, temperature, and monitoring requirements for carcasses and raw meat products, or with alternative procedures which would be permitted under this proposal. The written plan would include the establishment's designated control points, corrective actions, and, when applicable, the name of the processing authority. Some establishments may decide to hire a processing authority to develop such plans, while others may prepare their own plan. If an establishment chooses to follow alternative procedures, the establishment must hire a processing authority to develop the alternative procedures.

The refrigeration requirements set forth in this proposed rule may result in costs associated with purchases of refrigeration facilities. Although all establishments must have cooler rooms and most have refrigerated vehicles for shipping product, some small establishments may not have existing refrigeration facilities that would meet the proposed refrigeration requirements. The number and size of refrigeration units that may be required would depend on cooler room sizes and slaughter volumes of individual establishments.

Establishments would be required to monitor the temperatures of carcasses and raw meat products throughout their operations to ensure compliance with their plan, and maintain ongoing monitoring records for the previous 6 months. Costs for time/temperature requirements are estimated at $28.8 million.

4. Microbiological Testing for *Salmonella*

Each establishment that slaughters livestock or poultry or produces raw, ground meat or poultry products would be required to collect and test one specimen of product per day at the end of the production process. The specimen would be tested for the presence of *Salmonella* (the target organism). Testing could be conducted in the establishment's own laboratory or in a commercial/contract laboratory. Results of the testing would be recorded daily. Costs for this activity are estimated at $91.1 million.

As a general matter, this approach to process control verification testing provides a very efficient means of determining whether a slaughter establishment is consistently achieving the interim target for pathogen reduction. Many slaughter establishments currently conduct voluntarily, for a variety of purposes, significantly more frequent microbiological testing, and for many establishments the cost of testing a single sample per species per day will be relatively small (approximately $30–35 per sample) in relation to the volume of a day's production.

For some small FSIS-inspected establishments, however, microbiological testing may be entirely new, and the cost of testing will be more significant in relation to the volume of production. For example, some specialty slaughter plants may slaughter only a few head of livestock per day and may slaughter multiple species, thus requiring multiple tests, despite a low volume of production.

FSIS has considered the potential impact of its proposed microbiological testing requirement on small businesses. FSIS is considering alternatives to minimize the burden on small establishments while still achieving the goal of verifying that the establishment's process control is achieving the interim target for pathogen reduction.

One alternative would be to allow certain small establishments additional time to prepare for and begin testing. FSIS is proposing that testing begin 90 days after publication of the final rule. By extending this period for small establishments, such establishments would have additional time to prepare for the testing and to find an efficient means of accomplishing it. In addition, as the testing gets underway in most establishments and the demand for efficient testing increases, FSIS expects that the market will respond by producing increasingly economical test methods for use by establishment personnel and increasingly low-cost laboratory services for establishments that choose to contract outside the establishment for microbiological testing.

Another alternative for reducing the cost burden on small establishments would be to require less than daily testing to verify process control. For example, every-other-day testing could reduce costs by half. This would extend the time required to detect that any establishment is not achieving the target and to begin corrective measures.

FSIS invites comment on whether special consideration should be given to small establishments to reduce the cost burden of testing and on the alternatives outlined above, as well as any other possible alternatives. FSIS is particularly interested in comment on the criteria that should govern eligibility for such special consideration. As discussed above, for the purpose of allowing small establishments the maximum 3-year period to comply with the proposed HACCP regulation, FSIS is proposing to define a ''small'' establishment as one with annual sales of $2.5 million or below. FSIS invites comment on whether this would be the right criterion for any special relief regarding testing or whether an alternative criterion, such as the number of head or a different dollar volume of sales, should be used.

Long-Term Requirement

Implementation of HACCP Systems

Establishments would be required to develop and implement HACCP systems. Costs to develop, implement, and monitor HACCP plans for small establishments are estimated to be $157.6 million. FSIS has determined that it is reasonable to allow small establishments additional time to meet the proposed HACCP requirements. Therefore, small establishments would have 36 months from the publication date of the regulation to implement their HACCP plan(s).

D. Paperwork Requirements

The paperwork requirements in the current proposal, namely records and plans, represent an alternative to the current process of inspection. The industry's documentation of its processes, first in a plan and thereafter in a continuous record of process performance, is a more effective food safety approach than the sporadic generating of information by an inspector. It gives inspectors a much broader picture of production than they can generate on their own and gives them time to perform higher priority

tasks. At the same time it gives the managers a better view of their own process and more opportunity to adjust it to prevent safety defects.

To produce this documentation, all industry managers must learn about the options and methods for making their processes safer, which they do not have to do if the inspector appears to be the only one responsible for finding defects. Therefore, while the proposal contains increased paperwork burden, it is balanced by a reduction in the number of face-to-face contacts between management and the inspector that are required to assure the process is being controlled, so that the opportunity for better control is accompanied by an increase in productivity for both inspectors and managers.

In order not to increase the paperwork burden unnecessarily, the Agency has not required that plans be submitted for prior approval. In addition, the Agency is considering changing some existing prior approval programs, which would further reduce the paperwork burden on industry.

As part of establishments' sanitation requirements, each establishment would develop and maintain an SOP that would be used by inspection personnel in performing verification tasks. The SOP's would specify the cleaning and sanitizing procedures for all equipment and facilities involved in the production of every product. As part of the SOP, establishment employees(s) would record results of daily sanitation checks on a checklist at the frequencies stated in the SOP. The checklist would include both preoperational sanitation checks and operational sanitation checks. This checklist would be made available to Program employees, upon request.

As part of the time and temperature requirements, establishments would develop, implement, and place on file a written plan to meet the time and temperature requirements. The plan would include the establishments designated control points where temperatures would be measured; monitoring procedures; how recordkeeping activities would be performed; standards for control points (e.g., cooling rate, holding temperature, and shipping temperature); corrective actions; and, when applicable, the name of the processing authority.

Establishment employees would also have to maintain records that report the maximum temperature of carcasses and raw meat and poultry products throughout the establishment's operations on a daily basis with the frequency of monitoring based on the establishment's size and type of operation. These records would be required to be maintained on file for 6 months after the temperature measurement, and the records would be made available to Program employees, upon request. Additionally, the shipping establishment would be required to record the date and time of shipment of product on the waybill, running slip, conductor's card, shipper's certificate, or any other such papers accompanying the shipment.

As part of microbiological testing, each establishment would develop written procedures outlining specimen collection and handling. An establishment may test the specimens in their own laboratory or in a commercial/contract laboratory. Either an internal or external QA/QC program with check sample analysis would be required. QA/QC records must be available to Program employees, upon request.

The laboratory would supply the results on a daily basis to the establishment. The establishment would be responsible for entering the results daily into a statistical process control chart. The data and chart would be available for review by the Inspector in Charge upon request.

The establishment would notify the Inspector in Charge if the results of the testing exceed the process control limits. In such instances, a complete review by the establishment of the production process would be required. A written report of the evaluation, including the reason for process failure and proposed corrective actions, would be submitted to the Inspector in Charge within 14 days from the day the process exceeded the limits. This report would be updated on a weekly basis until the process is in control.

For the implementation of HACCP, the establishment would maintain on file the name and a brief resume of the HACCP-trained individual(s) who participates in the hazard analysis and subsequent development of the HACCP plans. Establishments would develop written HACCP plans that include: Identification of the processing step(s) presents hazard(s); identification and description of the CCP for each identified hazard; specification of the critical limit which may not be exceeded at the CCP, and, if appropriate, a target limit; description of the monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded; description of the records which would be generated and maintained regarding this CCP; and description of the establishment verification activities and the frequency at which they are to be conducted. Critical limits which are currently a part of FSIS regulations or other requirements must be included.

Establishments would keep records for measurements during slaughter and processing, corrective actions, verification check results, and related activities that contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The information would be recorded at the time that it is observed, and the record would be signed by the operator or observer.

The HACCP records would be reviewed by an establishment employee other than the one who produced the record, before the product is distributed in commerce. If a HACCP-trained individual is on-site, that person should be this second reviewer. The reviewer would sign the records. Lastly, HACCP records generated by the processor would be retained on site for at least 1 year and either on site or in a nearby location for an additional two years.

The paperwork and recordkeeping requirements contained in this proposed rule have been submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Send written comments to: Office of Management and Budget, Desk Officer for FSIS, Office of Information and Regulatory Affairs, Room 3208, New Executive Office Building, Washington, DC 20503, and to the Clearance Officer, Room 404–W, Administration Building, Washington, DC 20250.

Imports and Exports

The proposed rules will affect importers and exporters of meat and poultry to the U.S. The inspection statutes require that imported product be produced under an inspection system that is equivalent to the U.S. inspection system. The equivalence of a country's system must be established by the United States before product can be exported to the United States. The notion of equivalence has been clarified under the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary measures. Under the WTO all members have an obligation to apply the principle of equivalence on importing countries. Equivalence determinations are based on scientific evidence and risk assessment methodologies.

In light of the WTO emphasis on the use of science to determine equivalence, a number of countries are moving toward implementation of HACCP systems.

HACCP and the related near-term initiatives proposed in this document represent science-based regulation.

Upon implementation of these regulations, FSIS will review other countries' meat and poultry systems to ensure that exporting countries have adopted comparable measures, which would entitle them to continue exporting product to the United States. As other countries improve their regulations by adopting provisions comparable to those proposed in this document, it is expected that U.S. exports will similarly be affected.

FSIS is soliciting comments from all interested parties on how the proposed rule would affect international trade. FSIS believes that these improved scientific measures will facilitate trade.

Comments

Interested persons are invited to submit written comments concerning this proposal and the PRIA. Written comments should be sent in triplicate to Diane Moore, Docket Clerk, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 3171–S, Washington, DC 20250. Any person desiring an opportunity for an oral presentation of views as provided by the Poultry Products Inspection Act should make such request to the appropriate party listed under **FOR FURTHER INFORMATION CONTACT** so that arrangements can be made for such views to be presented. A record will be made of all views orally presented. All comments submitted in response to this proposal will be available for public inspection in the Docket Clerk's office from 8:30 a.m. to 1:00 p.m. and 2:00 p.m. to 4:00 p.m., Monday through Friday.

Copies of documents listed under ''References,'' below, are available for public inspection in the FSIS Docket Room, USDA, 14th and Independence Avenue, SW, Room 3175, South Agriculture Building, Washington, DC 20250.

V. References

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VI. Proposed Rules

List of Subjects

9 CFR Part 308

Meat inspection, Sanitation.

9 CFR Part 310

Antimicrobial treatment, Microbial testing, Reporting and Recordkeeping requirements.

9 CFR Part 318

Meat inspection, Reporting and Recordkeeping requirements, Reinspection, Processed products, Microbial testing.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 325

Meat inspection, Reporting and recordkeeping requirements, transportation.

9 CFR Part 326

Hazard Analysis and Critical Control Point (HACCP) systems, Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 327

Imported products, Hazard Analysis and Critical Control Point (HACCP) systems.

9 CFR Part 381

Sanitation, Antimicrobial treatment, Microbial testing, Reinspection, Processed products, Reporting and recordkeeping, Hazard Analysis and Critical Control Point (HACCP) systems, Imports, Transportation.

For the reasons set forth in the preamble, 9 CFR chapter III is proposed to be amended as follows:

PART 308—SANITATION

1. The authority citation for part 308 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 308.3 would be amended by redesignating paragraphs (b) through (i) as paragraphs (c) through (j), and adding a new paragraph (b) to read as follows:

§ 308.3 Establishments; sanitary conditions; requirements.

* * * * *

(b) The establishment shall develop and maintain written Sanitation Standard Operating Procedures (Sanitation-SOP's) which must be available to program employees for verification and monitoring. Sanitation-SOP's shall at a minimum detail daily sanitation procedures to be conducted before and during operations, to prevent direct contamination or adulteration of product(s). Sanitation SOP's must also identify plant officials responsible for monitoring daily sanitation activities, evaluating the effectiveness of SOP's, and initiating corrective actions when needed.

(1) A ''U.S. Rejected'' tag will be attached to the applicable equipment, utensil, room or compartment if a program employee determines that the establishment has failed to adhere to the sanitation SOP's specifically required by FSIS regulations. No equipment, utensil, room or compartment so tagged shall be used until reinspected and found acceptable by a Program employee.

(2) The establishment owner or operator shall be responsible for the establishment's adherence to the SOP's, as well as for all sanitary requirements specified elsewhere in these regulations. Preoperational procedures prescribed in the Sanitation-SOP's must be completed before the start of operations.

(3) The establishment shall develop and maintain a daily record of completion of all sanitation Standard Operating Procedures. Daily records, including any deviations from regulatory requirements and corrective actions taken shall be maintained by the establishment for a minimum of 6 months.

* * * * *

PART 310—POSTMORTEM INSPECTION

3. The authority citation for part 310 would continue to read as follows:

Authority: 21 U.S.C. 601–695, 7 CFR 2.17, 2.55.

4. Part 310 would be amended by adding §§ 310.24 and 310.25 to read as follows:

§ 310.24 Treating carcasses to reduce bacteria.

(a) *General.* Raw livestock carcasses shall be treated at least once at any point during the slaughter and dressing operation, but prior to entering the cooler to reduce levels of bacteria on carcass surfaces.

(b) *Treatment methods.* Official establishments may use any of the following treatment methods to reduce bacteria, provided that equipment has been approved under § 308.5, and that operation of the method results in full compliance with the Act and this subchapter.

(1) Any chlorine compound approved by the Administrator and administered to raw, uncooled whole livestock carcasses or major carcass portions at 20 to 50 parts per million (ppm) in the intake water at the final wash. The chlorinated water must contact all carcass surfaces. The Administrator will prepare a list containing compounds approved for use in official establishments. A copy of the list may be obtained from the Compounds and Packaging Branch, Produce Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700.

(2) Hot water applied such that the temperature of the water at the carcass surface is ≥165 °F (≥74 °C) for ≥10 seconds. The hot water must contact all carcass surfaces.

(3) Any antimicrobial compound listed in the table in § 318.7(c)(4) and permitted for use on livestock products may be used under the conditions specified therein. The antimicrobial compound must be administered so that it contacts all carcass surfaces.

(4) Any antimicrobial compound previously approved for use in livestock or livestock products as a food additive or processing aid by the Food and Drug Administration and listed in title 21 of the Code of Federal Regulations, parts 73, 74, 81, 172, 173, 182, or 184 may be used, provided the owner or operator has received approval for such use from the Administrator in accordance with § 318.7(a) of this subchapter. Any such antimicrobial compound must be administered so that it contacts all carcass surfaces.

(c) *Exemptions for exported product.* Product designated for export only to a country which will not accept product exposed to the antimicrobial treatment installed in the establishment will be exempted by the inspection program from the requirement for antimicrobial treatment if the product is properly identified, segregated, and labeled.

§ 310.25 Microbial testing.

(a) *General.* (1) *Incidental sampling.* In the event of an outbreak of foodborne disease or other evidence of a threat to public health attributable to a meat or meat food product, the Administrator will conduct a sampling and testing program as may be required. Carcasses at official establishments may be included in such a sampling and testing

program. Procedures and protocols will vary, depending on the pathogen of concern and other circumstances.

(2) *Rountine sampling.* (i) All establishments which have slaughter operations or produce raw, ground meat or raw sausages are required to collect a minimum of one sample for testing each day from each slaughter class and/or species of ground meat. Establishments shall test the samples for *Salmonella* species. The results of the analysis shall be provided to FSIS, as well as to the establishment. The results of the analysis shall be entered by the establishment in a moving sum verification chart or table as provided in paragraph (d)(2) of this section for review by Program employees.

(ii) Establishment must evaluate and improve their process controls when their performance, as indicated by the number of positive samples over a specified time, exceeds established acceptable limits.

(iii) Establishments which have adopted a Hazard Analysis and Critical Control Point system documenting that product being produced meets or exceeds the established targets for pathogen reduction may, upon approval by the Administrator, continue their current operating procedure in lieu of the proposed testing verification program set forth in paragraph (a)(2)(i) of this section.

(b) *Sample collection.* (1) Each establishment shall prepare written procedures outlining specimen collection. Procedures shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to Program employees for verification that it is being followed.

(2) The establishment will designate an employee or agent to collect the specimen, as follows:

(i) Samples from raw carcasses must be taken from chilled product in the cooler, or if to be used for further processing without cooling, prior to such further processing. Samples will be excised brisket skin tissue, 4 inches (10 cm) × 4 inches (10 cm) × ½ inch (1 cm) for beef and belly skin tissue, and 3 inches (7 cm) × 5 inches (12 cm) × ½ inch (1 cm) for hogs.

(ii) Samples from raw, ground or comminuted meat products should be taken prior to packaging. Samples will be ½ pound (0.4 kg).

(c) *Analysis.* (1) An establishment may test the specimens in its own laboratory or in a commercial/contract laboratory. However, the laboratory which is selected must demonstrate experience in testing meat and poultry for *Salmonella* spp. Either an internal or external quality assurance/quality control (QA/QC) program with check sample analysis is required. QA/QC records must be available to FSIS personnel and FSIS reserves the right to send official check samples to the laboratory to verify laboratory capabilities.

(2) The method used for analyzing a sample for *Salmonella* must be one of the following:

(i) The method published by FSIS in the current edition of the Microbiology Laboratory Guidebook. A copy of this method may be obtained from Microbiology Division, Science and Technology, FSIS, Washington, DC 20250.

(ii) Any method for *Salmonella* species recognized by the Association of Official Analytical Chemists or other scientific body that may be approved by the Administrator for this purpose. The analytic method used must be accepted by this third party authority as being at least as sensitive as the method used by FSIS for official samples.

(d) *Reports and recordkeeping.* (1) The designated laboratory or establishment employee will record the results and supply them on a daily basis to the establishment. The establishment will provide the results, at least weekly, to Program employees. The results may be electronically transmitted.

(2) The establishment will be responsible for entering the results into a moving sum verification chart or table. The moving sum process verification chart or table will be maintained by the establishment for each type of production (slaughter class and/or species of ground product). This table or chart will consist of a moving sum of results (i.e., a moving count of positives) that is updated with each new result. The moving sum procedure is determined by width of window (n) in terms of number of days' results to include, and maximum acceptable number of positive samples during that time frame or the Acceptable Limit.

(i) An example of a moving sum process control chart with the corresponding decision about process acceptability is given below. In the example, the window is 8 days (n=8), and the maximum number of positives permitted in that window is 3 (AL=3).

Day No.	Test result	Moving sum	Comparison to AL	Days included
1	0	0	Meets	1
2	0	0	Meets	1, 2
3	0	0	Meets	1 to 3
4	1	1	Meets	1 to 4
5	0	1	Meets	1 to 5
6	0	1	Meets	1 to 6
7	1	2	Meets	1 to 7
8	0	2	Meets	1 to 8
9	0	2	Meets	2 to 9
10	0	2	Meets	3 to 10
11	0	2	Meets	4 to 11
12	0	1	Meets	5 to 12
13	0	1	Meets	6 to 13
14	0	1	Meets	7 to 14
15	0	0	Meets	8 to 15

Note: Thus, the moving sum value for day 10 is the sum of the results in the 8 day window ending that day; it can be calculated simply by counting the number of 1's in the daily result column on days 3 through 10.

(ii) The chart below specifies the initial values of width of windows (n) and Acceptable Limit (AL) for each product class.

Commodity	Moving sum rules		
	Target (percent positive for *Salmonella*)	Window size (n) in days	Acceptable limit (AL)
Steers/Heifers ...	1	82	1
Raw Ground Beef	4	38	2
Cows/Bulls	1	82	1
Hogs	18	17	4
Fresh Pork Sausages	12	19	3

(e) *Corrective action.* (1) Establishments failing to meet Acceptable Limits will be presumed to have process control deficiencies. In such instances, a complete review by the establishment of the production process is required. A written report of the evaluation, including the reason for process failure and proposed corrective actions, will be submitted to the Inspector in Charge within 14 days from the day the process exceeded the limits. This report shall be updated on a weekly basis until the moving sum procedure indicates the process is in control.

(2) During the time the results fail to meet the Acceptable Limits, sampling should be conducted at a rate of two specimens or more per day. The sampling rate will return to normal when the establishment meets Acceptable Limits indicating the process is in control.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

5. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

* * * * *

6. Part 318 would be amended by adding a new § 318.25 to read as follows:

§ 318.25 Temperatures and chilling requirements for carcasses and raw meat products.

(a) *Definitions:*

Processing authority. A person or organization having expert knowledge of food processing procedures, having access to facilities for evaluating the safety of such procedures, and designated by the establishment to perform certain functions as indicated in this section.

Raw meat product. Any meat, meat food product, or meat byproduct that has not received treatment, such as cooking, to make it ready to eat.

Ready-to-eat-process. Any process, such as cooking, applied to a raw meat product that effectively inactivates infective pathogenic hazards that may be in or on the product.

Ready-to-eat product. Any food that is safe for human consumption without additional treatment.

(b) *Time and temperature requirements.* (1) All carcasses and raw meat products from such carcasses shall be cooled to surface temperatures of 50°F (10°C) or below within 5 hours and 40°F (4.4°C) or below within 24 hours from the time the carcasses exit the slaughter floor, unless such product immediately enters a ready-to-eat process or is part of a hot-boning operation, as prescribed in paragraph (b)(2) of this section. Raw product removed from the carcass on the slaughter floor not entering a ready-to-eat process or hot-boning operation, e.g., livers, hearts, and heads with cheek meat, shall be placed in a chiller within 1 hour of removal from the carcass.

(2) Establishments that separate raw meat from the bone before cooling the carcasses (hot-boning) shall cool such raw meat until it reaches an internal temperature of 50°F (10°C) or below within 5 hours of initial separation, and 40°F within 24 hours, except that raw meat from a hot-boning operation may enter a ready-to-eat process at the establishment within 5 hours of initial separation.

(3) Carcasses or raw meat products received at official establishments shall register an internal temperature of 40°F or below.

(4) Establishments shall maintain carcasses or raw meat products in their possession or under their control at a temperature of 40°F or below. Product may not be released into commerce unless chilled to this temperature.

(5) Establishments may use a processing authority to develop time and temperature limits microbiologically equivalent to those provided in paragraphs 318.25 (b)(1) through (b)(4). Any such time and temperature alternatives must be included in the establishment's written plan, as provided in § 318.25(c) of this section.

(c) *Temperature monitoring and written plans.* (1) Establishments shall monitor the temperature of raw meat at the control points as set forth in the establishment's written plan required by paragraph (c)(3) of this section. Establishments shall make the temperature monitoring records available to the Program employees and shall retain records up to 6 months after the temperature measurement or until such time as may otherwise be specified by the Administrator.

(2) To demonstrate compliance with the time and temperature requirements set forth in this section, establishments shall use temperature measuring devices readable and accurate to 2°F (0.9°C).

(3) Establishments shall develop, implement, and place on file a written plan for complying with the time and temperature requirements set forth in this section. Establishments shall make their plans and records, created under the plans, available to Program employees upon request. Each plan shall identify the establishment's control points, i.e., points designated in the production process after the chilling procedure where temperatures are measured; monitoring procedures, including frequency within a day's operation; records; standards for the control points, including cooling rate and holding temperature; corrective actions, including a system for separating and identifying noncomplying products; and, when applicable, the name of the processing authority.

PART 320—RECORDS, REGISTRATION, AND REPORTS

7. The authority citation for part 320 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

8. Section 320.1 would be amended by adding new paragraphs (b) (11), (12), (13) and (14) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(11) Standard operating procedures (SOP's) for sanitation, and daily records, as prescribed in § 308.3 of this subchapter.

(12) Temperature control plans and records, as required by § 318.25 of this subchapter.

(13) A written protocol for sampling raw product for pathogen testing, as required by § 318.25 of this subchapter.

(14) HACCP plans and records, as required by part 326 of this subchapter.

9. Section 320.3 would be amended by adding new paragraphs (c), (d) and (e) to read as follows:

§ 320.3 Record retention period.

* * * * *

(c) The Sanitation Standard Operation Procedures for Sanitation shall be retained as required in § 308.3.

(d) Temperature monitoring plan and records shall be retained as required in § 318.25(e)(1).

(e) Record of HACCP plans and systems, shall be retained as required in § 326.6(d).

10. Section 320.6 would be amended by revising paragraph (a) to read as follows:

§ 320.6 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, antimicrobial treatments, mandatory microbiological testing, and other aspects of the operations of the establishment and the conduct of inspection thereat, as may be required by the Administrator in special cases.

* * * * *

PART 325—TRANSPORTATION

11. The authority citation for part 325 would continue to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

12. Section 325.9 would be added to read as follows:

§ 325.9 Shipment of carcasses and raw meat products.

(a) Carcasses and raw meat products, as defined in § 318.25 of this subchapter, shall have an internal temperature of 40°F or below when loaded on vehicles for shipping. Such products that are shipped from an official establishment to another official establishment shall arrive at the receiving establishment at an internal temperature of 40°F or below.

(b) The date and time of shipment of carcasses and raw meat products from an official establishment to another official establishment shall be recorded on the waybill, running slip, conductor's card, shipper's certificate, or any other such papers accompanying a shipment.

13. A new part 326 would be added to read as follows:

PART 326—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

Sec.

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 326.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Criterion. A requirement on which a judgment or decision can be based.

Critical control point (CCP). A point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical control point (CCP) failure. Inadequate control at a CCP resulting in an unacceptable risk of a hazard.

Critical limit. A criterion that must be met for each preventive measure associated with a CCP.

Deviation. Failure to meet a critical limit.

HACCP. A hazard analysis and critical control point (HACCP) system that identifies specific hazards and preventive measures for their control to ensure the safety of food.

HACCP plan. The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.

HACCP system. The result of the implementation of the HACCP plan.

HACCP-trained individual. A person who has successfully completed a recognized HACCP course in the application of HACCP principles to meat processing operations, and who is employed by the establishment. A HACCP-trained individual must have sufficient experience and training in the technical aspects of food processing and the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question.

Hazard. A biological, chemical, or physical property that may cause a food to be unsafe for consumption.

Hazard analysis. The identification of any biological, chemical, or physical properties in raw materials and processing steps and an assessment of their likely occurrence and seriousness to cause the food to be unsafe for consumption.

Monitor. To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Preventive measures. Physical, chemical, or other factors that can be used to control an identified health hazard.

Process. A procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products wherein all CCPs are identical, except that optional operations or CCPs, such as packaging, may be applied to one or more of those products within the group.

Product. Any carcass, meat, meat byproduct, or meat food product capable of use as human food.

Recognized HACCP course. A HACCP course available to meat and poultry industry employees which satisfies the following: consists of at least 3 days, 1 day devoted to understanding the seven principles of HACCP, 1 day devoted to applying these concepts to this and other regulatory requirements of FSIS, and 1 day devoted to beginning development of a HACCP plan for a specific process.

Responsible establishment official. The management official located on-site at the establishment who is responsible for the establishment's compliance with this part.

Validation. An analysis of verification procedures, HACCP plan components, and an evaluation of records associated with the HACCP system to determine its efficacy for the production of safe and wholesome product for which the process was designed.

Verification. The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.

§ 326.2 Development of HACCP plan.

(a) Every official establishment shall develop, implement, and operate a HACCP plan, as set forth in paragraph (d) of this section, for each process listed below conducted by the establishment.

Categories of Processes for HACCP:

01 Raw-Ground
02 Raw Other Inclusive
03 Thermally Processed/Commercial Sterile
04 All Other Shelf Stable, Not Heat Treated
05 Fully Cooked—Not Shelf Stable
06 All Other Shelf Stable, Heat Treated
07 All Non-Shelf Stable, Heat Treated, Not Fully Cooked
08 Non-Shelf Stable, w/Secondary Inhibitors
09 Slaughter, All Meat Species

(b) At a minimum, the HACCP plan(s) shall be developed with the assistance

of a HACCP-trained individual employed by the establishment, whose name and resume is on file at the establishment, and who is knowledgeable of each process conducted by the establishment. The person(s) developing the plan shall be knowledgeable of HACCP and the associated recordkeeping procedures, and shall be capable of: identifying the hazards of the establishment's process and understanding the source of such hazards; establishing relevant CCP's throughout the process; and developing appropriate critical limits, monitoring procedures, corrective action procedures, verification procedures and their frequency, and operating procedures to implement the HACCP plan.

(c) Prior to the initiation of the Hazard Analysis phase for HACCP plan development, each establishment shall have on file a copy of its procedures for maintaining adherence to recommended Standard Operating Procedures for sanitation as set forth in § 308.3.

(d) The development of the HACCP plan shall consist of two stages: a Hazard Analysis, as provided under Principle 1 in § 326.3(a); and the development of the remainder of the HACCP plan for each specific process, as defined in § 326.2(a), including activities designed to ensure that the HACCP plan as developed is valid. These steps shall be completed over a period not to exceed 6 months prior to the phase-in date of the process category as prescribed in § 326.7, or upon application for the grant of inspection, or when a new process is intended for implementation.

(1) The HACCP plan should be in a format that is similar to the National Advisory Committee on Microbiological Criteria for Foods and FSIS generic models to ensure that both the establishment and program employees can readily identify the requirements in §§ 326.2(c) and 326.3.

(2) Each HACCP principle, as prescribed in § 326.3, must be included in the HACCP plan.

§ 326.3 HACCP principles.

The following principles and their associated components shall be included in each HACCP plan:

(a) *Principle No. 1.* A hazard analysis shall be conducted to identify biological (including microbiological), chemical, and/or physical properties of raw materials and processing steps that may cause a product or products to be unsafe for consumption. A list of steps in the process where potentially significant hazards may occur and the preventive measures to be taken shall be prepared. Hazard analysis should take into consideration factors such as: ingredients; physical characteristics and composition; processing procedures, microbial content of the product or products; facility and equipment design; packaging; sanitation; conditions of storage between packaging and the end user; intended use; and intended consumer. All identified hazards associated with each step in the process must be listed and its significant risk and severity evaluated. The preventive measures to control the identified hazards must be listed. The steps in application of this principle shall, at a minimum, include:

(1) A flow chart describing the steps of each process and product flow in the establishment; and

(2) Identification of the intended use and consumers of the product based upon normal use by the general public or a particular segment of the population.

(b) *Principle No. 2.* Identify the CCP's in the process using a decision tree and the information derived from § 326.3(a). CCP's shall be identified for purposes of product safety only. They must include physical, chemical, and biological (including microbiological and residue) hazards; must encompass the health and safety process control points required by FSIS regulations, or their equivalents; and must be specified for each identified hazard.

(c) *Principle No. 3.* Establish specific critical limits for preventive measures associated with each identified CCP. Critical limits which are a part of other portions of relevant regulations must be included.

(1) All critical limits shall meet or exceed any requirement set forth in this subchapter pertaining to a specific process and which are currently a part of FSIS regulations or other FSIS requirements.

(2) The responsible establishment official shall ensure that the critical limits are sufficient to control the identified hazards through a validation process consisting of verification and monitoring activities.

(d) *Principle No. 4.* Establish CCP monitoring requirements. Establish specific procedures for using the results of CCP monitoring to adjust and maintain process control.

(1) The responsible establishment official shall ensure that establishment employees are assigned to monitor each CCP effectively, as determined by Hazard Analysis.

(2) When monitoring is not possible on a continuous basis, the monitoring interval established shall reliably indicate that the hazard can be controlled as demonstrated by process validation performed during the Hazard Analysis and plan development.

(3) All records and documents associated with CCP monitoring shall be dated and signed or initialed by the person(s) conducting the monitoring.

(e) *Principal No. 5.* Establish corrective action(s) to be taken when monitoring indicates that there is a deviation from an established critical limit.

(1) The corrective actions shall describe the step(s) taken to identify and correct the cause of noncompliance to assure that the CCP is under control, ensure that no safety hazards exist after these actions, and define measures to prevent recurrence.

(2) Corrective actions shall include a determination of the effect of the deviation(s) on product safety; how noncompliant product will be handled, including segregation and holding procedures; a definition of lot size; whether the deviation indicates a modification or revision of the HACCP plan is required, and time frames for modification or revision of the HACCP plan.

(f) *Principal No. 6.* Establish effective recordkeeping and systematic review procedures that document the HACCP system. The required records are specified in § 326.6.

(g) *Principal No. 7.* Establish procedures for verification by a HACCP-trained individual that the HACCP system is functioning effectively to ensure product safety and process control. This is the plan validation process and therefore includes methods, procedures, or tests in addition to those used for monitoring. Such validation shall ensure:

(1) The adequacy of the critical limits at each CCP;

(2) The continuing effectiveness of the establishment's HACCP plan and system, including taking into account changes in product volumes, procedures, personnel, and product use;

(3) The accuracy of the HACCP plan through the completion of all seven principles and their associated actions including revalidation whenever significant product, process, deviations, or packaging changes require modification of the plan; and

(4) The evaluation of product safety in situations where the establishment identifies deviations from critical limits, all steps taken in response to a deviation, and the adequacy of the corrective response.

§ 326.4 Implementation of the HACCP plan.

(a) Upon completion of the Hazard Analysis and development of the HACCP plan, a responsible establishment official shall review and approve the written plan by signing it.

(b) Upon completion of the Hazard Analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended, ensuring the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions. During this initial HACCP plan validation period, the establishment shall conduct repeated verifications and meet frequently with Program employees to assure the HACCP system is functioning as intended, which shall include a review of the records generated by the HACCP system.

(c) When an ingredient change, product reformulation, manufacturing process or procedure modification, equipment change, or any other such change requires modifications to the establishment's HACCP plan, the responsible establishment official, in consultation with a HACCP-trained individual employed by the establishment, shall ensure that the HACCP plan is modified to reflect such changes. The development of the modified HACCP plan shall be conducted in accordance with §§ 326.2 and 326.3.

§ 326.5 Operation of HACCP system.

(a) The establishment's HACCP system, as set forth in the establishment's HACCP plan, shall be operated with the advice and guidance of a HACCP-trained individual, as defined in § 326.1.

(b) The responsible establishment official shall be held responsible for the operation of the HACCP system to ensure compliance with the Act and regulations thereunder. In all respects, however, the Administrator shall continue to provide the Federal inspection necessary to carry out the provisions of the Act.

§ 326.6 Record review and maintenance.

(a) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the time recorded, and the record shall be signed or initialed by the establishment employee making the entry. Prior to shipping product produced under each process, the establishment shall review, on a defined, systematic basis, all processing and production records associated with the HACCP plan to ensure completeness, to determine whether all critical limits were met and, if appropriate, corrective action(s) were taken, including proper disposition of product. This review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by the HACCP-trained individual, or the responsible establishment official.

(b) The following records supporting the establishment's HACCP plan shall be maintained:

(1) The written HACCP plan including all portions of the Hazard Analysis as prescribed in this part;

(2) Records associated with the monitoring of CCP's, which include the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), identity, or slaughter production lot; and date the record was made; and

(3) Records associated with supporting documentation for the Hazard Analysis, development of the selected CCP's, critical limits, frequency of monitoring and verification procedures, and corrective actions taken.

(c) All such records shall be made available to any Program employee upon request. A deviation from a critical limit shall be brought to the attention of the appropriate Program employee promptly.

(d) All records shall be retained at the establishment at all times, except that records for monitoring CCP's, corrective actions, and verification procedures shall be retained at the establishment for no less than 1 year, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees.

§ 326.7 Enforcement.

(a) *Implementation*. (1) The following establishments shall meet the requirements of this part by the date prescribed:

(i) Estabishments that conduct the following categories of processes shall comply by [insert date 12 months after publication of final rule]: Raw, Ground (including mechanically separated (species)); Thermally Processed/ Commercially Sterile; and All Other, Shelf Stable, Heat Treated.

(ii) Establishments that conduct the following categories of processes shall comply by (insert date 18 months after publication of final rule): Non-Shelf Stable, Heat Treated, Not Fully Cooked; and Shelf Stable, Not Heat Treated.

(iii) Establishments that conduct the following categories of processes shall comply by [insert date 24 months after publication of final rule]: Fully Cooked, Non-Shelf Stable; and Non-Shelf Stable, with Secondary Inhibitors.

(iv) Establishments that conduct the following categories of processes shall meet the requirements of this part by [insert date 30 months after publication of final rule]: Raw, other; and Slaughter, all livestock.

(v) Small entities that generate less than $2.5 million dollars of product per year shall comply by [insert date 36 months after publication of final rule].

(2) Any establishment that obtains Federal inspection on or after the effective date(s) for the process category(ies) to be conducted shall conduct a Hazard Analysis, and shall develop and validate its HACCP plan(s), as set forth in § 326.2(d) of this part, concurrent with the grant of inspection. Process analysis, as set forth in § 326.4(c), shall commence after obtaining Federal inspection to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(3) Any establishment that institutes a new process requiring development of a HACCP plan on or after the applicable effective date(s) of this regulation shall conduct all activities required for hazard analysis, development, and validation of its HACCP plan(s) for the process category(ies) as set forth in § 326.2(d) of this part, before commencing production and shall conduct process analyses, as set forth in § 326.4(b), to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(4) Commencing with the applicable effective date(s), the Program shall refuse new inspection services requested for, or, using the procedures in § 335.33, suspend inspection services from establishments or specific processes within establishments not having HACCP plans.

(b) *Verification*. The Program shall verify that HACCP plan(s) are effective and validated, and otherwise in compliance with this regulation. Such verification and process validation may include:

(1) Reviewing the HACCP plan,

(2) Reviewing the CCP records,

(3) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs,

(4) Conducting verification activities to determine whether CCP's are under control,

(5) Reviewing the critical limits,

(6) Reviewing other records pertaining to the HACCP plan or system,

(7) Random sample collection and analysis to determine the safety of the product, and/or

(8) On-site observations and records review for revalidation of HACCP plans.

(c) *Suspension, correction of invalid plans.* (1) If the Program finds a HACCP plan to be invalid, inspection service for the process covered by the HACCP plan will be suspended using the procedures in § 335.33. The processing facilities identified shall not be used for production of meat or meat food product pending completion of the specified corrective action(s), as prescribed (c)(3) of this section and written acknowledgement thereof by the designated Program official. Products produced by the process prior to the suspension suspected of being adulterated shall be retained at the establishment pending disposition by the Program, and if such product has been shipped, it shall be subject to voluntary recall as necessary to protect public health.

(2) A HACCP plan may be found invalid if:

(i) The HACCP plan does not meet the requirements of this part,

(ii) HACCP records are not being maintained as required to validate the plan or verify process control under the plan, or

(iii) A processing failure results in production of adulterated product.

(3) Invalid HACCP plans must be corrected by:

(i) Submission to the designated Program official of a written, detailed verification by a HACCP-trained individual that a modified HACCP plan has been developed in consultation with that individual and that, as modified, the plan corrects the deficiencies found, and

(ii) In the case of a processing deficiency resulting in production of adulterated product, submission to the designated Program official of and adherence to a written plan for finished product produced under the modified HACCP plan to be tested by an external laboratory for chemical or microbial characteristics, at the establishment's expense, as appropriate to demonstrate that the process under the modified HACCP plan corrects the identified problem.

(4) If the establishment fails to adhere to the modified HACCP plan and, if applicable, the testing plan, resulting in a subsequent suspension of the same process for the same or a related deficiency, the designated Program official will, upon receipt and before acknowledgement of any subsequent modified plan(s) under paragraph (c)(3) of this section, also review the establishment's performance under the inspection regulations generally and make a written recommendation to the Administrator whether any additional inspection or enforcement measures may be required.

PART 327—IMPORTED PRODUCTS

14. The authority citation for Part 327 would continue to read as follows:

Authority: 21 U.S.C. 601–695, 7 CFR 2.17, 2.55.

15. Section 327.2 would be amended by redesignating paragraph (a)(2)(ii)(*h*) as (a)(2)(ii)(*i*) and by adding a new paragraph a(2)(ii)(*h*) to read as follows:

§ 327.2 Eligibility of foreign countries for importation of products into the United States.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(*h*) Development and maintenance of a Hazard Analysis and Critical Control Point (HACCP) system pursuant to part 326 of this subchapter in each certified establishment;

* * * * *

16. Subpart E of part 335 would be redesignated as subpart F, and a new subpart E would be added to read as follows:

Subpart E—Rules Applicable to the Suspension of Inspection for Failure To Have a Validated HACCP Plan

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 335.33 Refusal or suspension of inspection service for failure to comply with HACCP requirements.

(a) In any situation in which the Administrator determines that an establishment which is applying for inspection or receiving inspection under Title I of the Federal Meat Inspection Act does not have a valid HACCP plan as required by § 326.7, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as ''inspected and passed.'' The Administrator shall notify the applicant or operator of the establishment, orally or in writing, as promptly as circumstances permit, of such refusal to inspect and pass the meat or meat food products and the reasons therefor, and the action which the Administrator deems necessary to have a valid HACCP plan. In the event of oral notification, written confirmation shall be given, as promptly as circumstances permit, to the applicant or operator of the establishment in the manner prescribed in § 1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(b) If any applicant or operator of an establishment so notified fails to take the necessary action to have a valid HACCP plan within the period specified in the notice, the Administrator may issue a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service shall be refused or withdrawn from such establishment pending final determination in the proceeding.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

17. The authority citation for Part 381 would continue to read as follows:

Authority: 7 U.S.C. 138F; 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.17, 2.55.

Subpart H—Sanitation

18. Section 381.45 would be revised to read as follows:

§ 381.45 Minimum standards for sanitation, facilities and operating procedures in official establishments.

The provisions of §§ 381.45 through 381.61, inclusive, shall apply with respect to all official establishments.

(a) The establishment shall develop and maintain written Sanitation Standard Operating Procedures (Sanitation SOP's) which must be available to program employees for verification and monitoring. Sanitation SOP's shall, at a minimum, detail daily sanitation procedures to be conducted, before and during operations, to prevent direct contamination or adulteration of product(s). Sanitation SOP's must also identify plant officials responsible for monitoring daily sanitation activities, evaluating the effectiveness of SOP's, and initiating corrective actions when needed.

(1) A ''US Rejected'' tag will be attached to the applicable equipment, utensil, room or compartment if a Program employee determines that the establishment has failed to adhere to the Sanitation SOP's specifically required by paragraph (a) of this section. No equipment, utensil, room, or compartment so tagged shall be used until reinspected and found acceptable by a Program employee. The establishment shall maintain daily records for a minimum of 6 months.

(2) The establishment owner or operator shall be responsible for the establishment's adherence to the SOP's, as well as for all sanitary requirements specified elsewhere in these regulations.

Preoperational procedures prescribed in the Sanitation SOP's must be completed before the start of operations.

(3) The establishment shall develop and maintain a daily record of completion of all sanitation Standard Operating Procedures. Daily records, including any deviations from regulatory requirements and corrective actions taken, shall be maintained by the establishment for a minimum of 6 months.

(b) [Reserved]

Subpart I—Operating Procedures

19. Section 381.66 would be amended by revising paragraph (b) to read as follows:

§ 381.66 Temperatures and chilling and freezing procedures.

* * * * *

(b) *General chilling requirements*—(1) *Definitions:*

Processing authority. A person or organization having expert knowledge of food processing procedures, having access to facilities for evaluating the safety of such procedures, and designated by the establishment to perform certain functions as indicated in this section.

Raw poultry product. Any poultry or poultry byproduct that has not received treatment, such as cooking, to make it ready to eat.

Ready-to-eat process. Any process, such as cooking, applied to a raw poultry product that effectively inactivates infective pathogenic hazards that may be in or on the product.

Ready-to-eat product. Any food that is safe for human consumption without additional treatment.

(2) *Time and temperature requirements.*

(i) All poultry and poultry products that are slaughtered and eviscerated in the official establishment shall be chilled immediately after processing to reach surface temperatures of 50 °F (10°C) or below within 1.5 hours and 40°F (4.4°C) or below within 24 hours from the time that the carcasses exit the slaughter line, unless such product immediately enters a ready-to-eat process or a hot-boning operation, as prescribed in paragraph (b)(2)(ii) of this section. Raw product removed from the carcass on the slaughter line, such as giblets, shall be placed in a chiller within 1 hour of removal from the carcass.

(ii) Establishments that separate raw poultry from the bone before cooling the carcasses (hot-boning) shall cool such raw poultry until it reaches an internal temperature of 50°F (10°C) or below within 1.5 hours of initial separation, except that raw poultry from a hot-boning operation may enter a ready-to-eat process at the establishment within 1.5 hours of initial separation.

(iii) Carcasses or raw poultry products received at official establishments shall register an internal temperature of 40°F or below.

(iv) Establishments shall maintain raw poultry carcasses and products in their possession or under their control at a temperature of 40°F or below. Product may not be released into commerce unless chilled to this temperature.

(v) Establishments may use a processing authority to develop time and temperature limits microbiologically equivalent to those provided in paragraphs 381.66(b)(2)(i) through (b)(2)(iv). Any such time and temperature alternatives must be included in the establishment's written plan, as provided in § 381.66(b)(3) of this section.

(3) *Temperature monitoring and written plans.* (i) Establishments shall monitor the temperature of raw poultry at the control points as set forth in the establishment's written plan required by paragraph (b)(3)(iii) of this section. Establishments shall make the temperature monitoring records available to Program employees and shall retain records up to 6 months after the temperature measurement or until such time as may otherwise be specified by the Administrator.

(ii) To demonstrate compliance with the time and temperature requirements set forth in this section, establishments shall use temperature measuring devices readable and accurate to 2°F (0.9°C).

(iii) Establishments shall develop, implement, and place on file a written plan for complying with the time and temperature requirements set forth in this section. Establishments shall make their plans and records, created under the plans, available to Program employees upon request. Each plan shall identify the establishment's control points, i.e., points designated in the production process after the chilling procedure where temperatures are measured; monitoring procedures, including frequency within a day's operation; records; standards for the control points, including cooling rate and holding temperature; corrective actions, including a system for separating and identifying noncomplying products; and, when applicable, the name of the processing authority.

* * * * *

20. Subpart I would be amended by adding a new § 381.69 to read as follows:

§ 381.69 Treating carcasses to reduce bacteria.

(a) *General.* Raw poultry carcasses shall be treated at least once at any point during the slaughter and dressing operation, but prior to entering the chiller to reduce levels of bacteria on carcass surfaces.

(b) *Treatment methods.* Official establishments may use any of the following treatment methods to reduce bacteria, provided that equipment has been approved under § 381.53, and that operation of the method results in full compliance with the Act and this part.

(1) Any chlorine compound approved by the Administrator and administered to raw, unchilled whole poultry carcasses or major carcass portions at 20 to 50 parts per million (ppm) in the intake water at the final wash. The chlorinated water must contact all carcass surfaces. The Administrator will prepare a list containing compounds approved for use in official establishments. A copy of the list may be obtained from the Compounds and Packaging Branch, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700.

(2) Hot water applied such that the temperature of the water at the carcass surface is ≥165°F (≥74°C) for ≥10 seconds. The hot water must contact all carcass surfaces.

(3) Any antimicrobial compound listed in the table in § 381.147(f)(4) and permitted for use on poultry products may be used under the conditions specified therein. The antimicrobial compound must be administered so that it contacts all carcass surfaces.

(4) Any antimicrobial compound approved for use in poultry or poultry products as a food additive or processing aid by the Food and Drug Administration and listed in title 21 of the Code of Federal Regulations, parts 73, 74, 81, 172, 173, 182, or 184 may be used, provided the owner or operator has received approval for such use from the Administrator in accordance with § 381.147(f)(2) of this part. Any such antimicrobial compound must be administered so that it contacts all carcass surfaces.

(5) If the application or use of an antimicrobial treatment is determined by the Inspector in Charge to not conform to approved parameters, the establishment shall make necessary adjustments within 15 minutes. If adjustments are not made within 15 minutes, the establishment shall suspend the treatment and shall not process carcasses until appropriate adjustments are made. If a second

antimicrobial treatment is in place and functioning properly, the use of the nonconforming antimicrobial treatment may be discontinued and processing of carcasses may continue. Product not treated in conformance with approved parameters shall be retained for disposition by the Inspector in Charge.

(c) *Exemptions for exported product.* Product designated for export only to a country which will not accept product exposed to the antimicrobial treatment installed in the establishment will be exempted by the inspection program from the requirement for antimicrobial treatment if the product is properly identified, segregated, and labeled.

Subpart K—Post Mortem Inspection: Disposition of Carcasses and Parts

21. In § 381.76, Table 1—Definitions of Nonconformances, would be amended in paragraph A–1 by removing the word ''feces'', by amending paragraph A–2 to remove the end note regarding feces, and by removing paragraph A–8, ''Feces ≥⅛'', and renumbering paragraphs A–9 through A–20 as A–8 through A–19.

22. Section 381.79 would be amended by revising the heading, redesignating the existing text as paragraph (a), and adding a new paragraph (b) to read as follows:

§ 381.79 Passing of carcasses; microbial testing.

(a) * * *

(b) *Microbial Testing*—(1) *General.*

(i) *Incidental sampling.* In the event of an outbreak of foodborne disease or other evidence of a threat to public health attributable to a poultry or poultry food product, the Administrator will conduct a sampling and testing program as may be required. Poultry at official establishments may be included in such a sampling and testing program. Procedures and protocols will vary, depending on the pathogen of concern and other circumstances.

(ii) *Routine sampling.*

(A) All establishments that have slaughter operations or produce raw, ground poultry are required to collect a minimum of one sample for testing each day from each slaughter class and/or species of ground poultry. The sample will be tested for *Salmonella* species. The results of the analysis will be provided to FSIS, as well as to the establishment. The results of the analysis will be entered by the establishment in a moving sum verification chart or table for review by Program employees.

(B) FSIS will require producers to evaluate and improve their process controls when their performance, as indicated by the number of positive samples over a specified time, exceeds established Acceptable Limits.

(C) Establishments that have adopted a Hazard Analysis and Critical Control Point system documenting that product being produced meets or exceeds the established targets for pathogen reduction may, upon approval by the Administrator, continue their current operating procedure in lieu of the proposed testing verification program, set forth in paragraph (b)(1)(ii)(C) of this section.

(2) *Sample collection.* (i) Each establishment will prepare written procedures outlining specimen collection. Procedures will address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure will be made available to Program employees for verification that it is being followed.

(ii) The establishment will designate an employee or agent to collect the specimen, as follows:

(A) Whole birds will be collected at the end of the chilling process, after the drip line, and rinsed in an amount of buffer appropriate for the type of bird sampled.

(B) Samples from raw ground poultry will be taken prior to packaging. Samples will be 1/2 pound (0.4 kg).

(3) *Analysis.* (i) An establishment may test the specimens in its own laboratory or in a commercial/contract laboratory. However, the laboratory which is selected must demonstrate experience in testing poultry for *Salmonella* spp. Either an internal or external quality assurance/quality control (QA/QC) program with check sample analysis is required. QA/QC records must be available to FSIS employees and FSIS reserves the right to send official check samples to the laboratory to verify laboratory capabilities.

(ii) The method used for analyzing a sample for *Salmonella* must be one of the following:

(A) The method published by FSIS in the current edition of the Microbiology Laboratory Guidebook. A copy of this method may be obtained from the Microbiology Division, Science and Technology, Food Safety and Inspection Service, Washington, DC 20250.

(B) Any method for *Salmonella* species recognized by the Association of Official Analytical Chemists or other recognized scientific body that may be approved by the Administrator for this purpose. The analytic method used must be accepted by this third party authority as being at least as sensitive as the method used by FSIS for official samples.

(4) *Reports and recordkeeping.* (i) The designated laboratory or establishment employee will record the test results and supply them on a daily basis to the establishment. The establishment will provide the results, at least weekly, to Program employees. The results may be electronically transmitted.

(ii) The establishment will be responsible for entering the results into a moving sum verification chart or table. The verification chart or table will be maintained by the establishment for each type of production (slaughter class and/or species of comminuted product). This chart or table will consist of a moving sum of results (i.e., a moving count of positives) that is updated with each new result. The moving sum procedure is determined by width of window (n) in terms of number of days' results to include, and maximum acceptable number of positives during that time frame.

(A) An example of a moving sum process control chart with the corresponding decision about process acceptability is given below. In the example, the window is 8 days (n=8), and the maximum number of positives permitted in that window is 3 (AL=3):

Day No.	Test result	Moving sum	Comparison to AL	Days included
1	0	0	Meets	1.
2	0	0	Meets	1, 2.
3	0	0	Meets	1 to 3.
4	1	1	Meets	1 to 4.
5	0	1	Meets	1 to 5.
6	0	1	Meets	1 to 6.
7	1	2	Meets	1 to 7.
8	0	2	Meets	1 to 8.
9	0	2	Meets	2 to 9.

Day No.	Test result	Moving sum	Comparison to AL	Days included
10	0	2	Meets	3 to 10.
11	0	2	Meets	4 to 11.
12	0	1	Meets	5 to 12.
13	0	1	Meets	6 to 13.
14	0	1	Meets	7 to 14.
15	0	0	Meets	8 to 15.

Note: Thus, the moving sum value for day 10 is the sum of the results in the 8 day window ending that day; it can be calculated simply by counting the number of 1's in the daily result column on days 3 through 10.

(B) The following chart specifies the initial values of width of windows (n) and Acceptable Limits (AL) for each product class:

Commodity	Moving sum rules		
	Target (percent positive for *Salmonella*)	Window size (n) in days	Acceptable limit (AL)
Broilers	25	16	5
Turkeys	15	15	3
Raw Ground Poultry	.....	.....	.....

(5) *Corrective action.* (i) Establishments not meeting Acceptable Limits will be presumed to have process control deficiencies. In such instances, a complete review by the establishment of the production process is required. A written report of the evaluation, including the reason for process failure and proposed corrective actions, will be submitted to the Inspector in Charge within 14 days from the day the process exceeded the limits. This report shall be updated on a weekly basis until the moving sum procedure indicates the process is in control.

(ii) During the time the results fail to meet the Acceptable Limits, sampling should be conducted at a rate of two specimens or more. The sampling rate will return to normal when the establishment meets Acceptable Limits, indicating the process is in control.

Subpart Q—Records, Registration, and Reports

23. Section 381.175 would be amended by adding new paragraphs (b)(6), (7), (8) and (9) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(6) Written Sanitation Standard Operating Procedures, and daily records, as prescribed in § 381.45 of this part.

(7) Temperature control plans and records, as required by § 381.66 of this subpart.

(8) Written protocol for sampling raw product for pathogen testing, as required by § 381.79 of this subpart.

(9) HACCP plans and records, as required by subpart Z of this part.

24. Section 381.177 would be amended by adding new paragraphs (c), (d) and (e) to read as follows:

§ 381.177 Record retention period.

* * * * *

(c) Standard Operating Procedures (SOP) for sanitation shall be retained as required in § 381.45 of this subchapter.

(d) Temperature monitoring plan and records shall be retained as required in § 381.66 of this subchapter.

(e) Records of HACCP plans and systems, as required by subpart Z of this part, shall be retained as required in § 381.606(d).

25. Section 381.180 would be amended by revising paragraph (a) to read as follows:

§ 381.180 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, antimicrobial treatments, mandatory microbiological testing, and other aspects of the operations of the establishment, and the conduct of inspection thereat as may be required by the Administrator in special cases.

* * * * *

Subpart S—Transportation; Exportation; Sale of Poultry or Poultry Products

26. Subpart S would be amended by adding a new § 381.188 to read as follows:

§ 381.188 Shipment of raw poultry and poultry products.

(a) Poultry carcasses and poultry products, as defined in § 381.66 of this part, shall have an internal temperature of 40°F or below when loaded on vehicles for shipping. Such products that are shipped from an official establishment to another official establishment shall arrive at the receiving establishment at an internal temperature of 40°F or below.

(b) The date and time of shipment of carcasses and raw poultry products from an official establishment to another official establishment shall be recorded on the waybill, running slip, conductor's card, shipper's certificate, or any other such papers accompanying a shipment.

Subpart T—Imported Poultry Products

27. Section 381.196 would be amended by redesignating paragraph (a)(2)(ii)(*h*) as paragraph (a)(2)(ii)(*i*) and by adding a new paragraph (a)(2)(ii)(*h*) to read as follows:

§ 381.196 Eligibility of foreign countries for importation of poultry products into the United States.

(a) * * *

(b) * * *

(ii) * * *

(*h*) Development and maintenance of a Hazard Analysis and Critical Control Point (HACCP) system pursuant to subpart Z of this part in each certified establishment; and

* * * * *

Subpart W—Rules of Practice Governing Proceedings Under the Poultry Products Inspection Act

28. Subpart W would be amended by adding a new undesignated center heading and a new § 381.237 to read as follows:

Rules Applicable to the Suspension of Inspection for Failure To Have a Validated HACCP Plan

§ 381.237 Refusal or suspension of inspection service under the PPIA for failure to comply with HACCP requirements.

(a) In any situation in which the Administrator determines that an establishment which is applying for inspection or receives inspection under the Poultry Products Inspection Act does not have a valid HACCP plan as required by § 381.607, he shall refuse to render inspection at the establishment.

The Administrator shall notify the applicant or operator of the establishment, orally or in writing, as promptly as circumstances permit, of such refusal and the reasons therefor, and the action which the Administrator deems necessary to have valid HACCP plan. In the event of oral notification, written confirmation shall be given, as promptly as circumstances permit, to the applicant or operator of the establishment in the manner prescribed in § 1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(b) If any applicant or operator of an establishment so notified fails to take the necessary action to have a valid HACCP plan within the period specified in the notice, the Administrator may issue a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service shall be refused or withdrawn from such establishment pending final determination in the proceeding.

30. A new subpart Z would be added to read as follows:

Subpart Z—Hazard Analysis and Critical Control Points (HACCP) System

Sec.

§ 381.601 Definitions.

For purposes of this subpart, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Criterion. A requirement on which a judgment or decision can be based.

Critical control point (CCP). A point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical control point (CCP) failure. Inadequate control at a CCP resulting in an unacceptable risk of a hazard.

Critical limit. A criterion that must be met for each preventive measure associated with a CCP.

Deviation. Failure to meet a critical limit.

HACCP. A hazard analysis and critical control point (HACCP) system that identifies specific hazards and preventive measures for their control to ensure the safety of food.

HACCP plan. The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.

HACCP-trained individual. A person who has successfully completed a recognized HACCP course in the application of HACCP principles to poultry processing operations, and who is employed by the establishment. A HACCP-trained individual must have sufficient experience and training in the technical aspects of food processing and the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question.

HACCP system. The result of the implementation of the HACCP plan.

Hazard. A biological, chemical, or physical property that may cause a food to be unsafe for consumption.

Hazard Analysis. The identification of any biological, chemical, or physical properties in raw materials and processing steps and an assessment of their likely occurrence and seriousness to cause the food to be unsafe for consumption.

Monitor. To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Preventive measures. Physical, chemical, or other factors that can be used to control an identified health hazard.

Process. A procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products wherein all CCP's are identical, except that optional operations or CCP's, such as packaging, may be applied to one or more of those products within the group.

Product. Any carcass, poultry, poultry byproduct, or poultry food product capable of use as human food.

Recognized HACCP course. A HACCP course available to meat and poultry industry employees which satisfies the following: consists of at least 3 days, 1 day devoted to understanding the seven principles of HACCP, 1 day devoted to applying these concepts to this and other regulatory requirements of FSIS, and 1 day devoted to development of a HACCP plan for a specified process.

Responsible establishment official. The management official located on-site at the establishment who is responsible for the establishment's compliance with this part.

Validation. An analysis of verification procedures, HACCP plan components, and an evaluation of records associated with the HACCP system to determine its efficacy for the production of safe and wholesome product for which the process was designed.

Verification. The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.

§ 381.602 Development of HACCP plan.

(a) Every official establishment shall develop, implement, and operate a HACCP plan, as set forth in paragraph (c) of this section, for each process listed below conducted by the establishment.

Categories of Processes for HACCP:

01 Raw-Ground
02 Raw Other—Inclusive
03 Thermally Processed/Commercially Sterile
04 All Other Shelf Stable, Not Heat Treated
05 Fully Cooked—Not Shelf Stable
06 All Other Shelf Stable, Heat Treated
07 All Non-Shelf Stable, Heat Treated, Not Fully Cooked
08 Non-Shelf Stable, w/Secondary Inhibitors
09 Slaughter—All Poultry Kind

(b) At a minimum, the HACCP plan(s) shall be developed with the assistance of a HACCP-trained individual employed by the establishment, whose name and resume is on file at the establishment, and who is knowledgeable of each process conducted by the establishment. The person(s) developing the plan shall be knowledgeable of HACCP and the associated recordkeeping procedures, and shall be capable of: identifying the hazards of the establishment's process and of understanding the source of such hazards; establishing relevant CCP's throughout the process; and developing appropriate critical limits, monitoring procedures, corrective action procedures, verification procedures and their frequency, and operating procedures to implement the HACCP plan.

(c) Prior to the initiation of the Hazard Analysis phase of HACCP plan development, each establishment shall have on file a copy of its procedures for maintaining adherence to recommended Standard Operating Procedures for sanitation as set forth in § 381.45.

(d) The development of the HACCP plan shall consist of two stages: a Hazard Analysis, as provided under Principle 1 in § 381.603(a); and the development of the remainder of the HACCP plan for each specific process as defined in § 381.602(a), including activities to ensure that the HACCP plan, as developed, is valid. These steps shall be completed over a period not to

exceed 6 months prior to the phase-in date of the process category, as prescribed in § 381.607, or upon application for the grant of inspection, or when a new process is intended for implementation.

(1) The HACCP plan should be in a format that is similar to the National Advisory Committee on Microbiological Criteria for Foods and FSIS generic models to ensure that both the establishment and program employees can readily identify the requirements in §§ 381.602(c) and 381.603.

(2) Each HACCP principle, as prescribed in § 381.603 must be included in the HACCP plan.

§ 381.603 HACCP principles.

The following principles and associated components shall be included in each HACCP plan:

(a) *Principle No. 1.* A hazard analysis shall be conducted to identify biological (including microbiological), chemical, and/or physical properties of raw materials and processing steps that may cause a product or products to be unsafe for consumption. A list of steps in the process where potentially significant hazards may occur and the preventive measures to be taken shall be prepared. Hazard analysis should take into consideration factors such as: ingredients; physical characteristics and composition; processing procedures; microbial content of the product or products; facility and equipment design; packaging; sanitation; conditions of storage between packaging and the end user; intended use; and intended consumer. All identified hazards associated with each step in the process must be listed and its significant risk and severity evaluated. The preventive measures to control identified hazards must be listed. The steps in application of this principle shall, at a minimum, include:

(1) A flow chart describing the steps of each process and product flow in the establishment; and

(2) Identification of the intended use and consumers of the product based upon normal use by the general public or a particular segment of the population.

(b) *Principle No. 2.* Identify the CCP's in the process using a decision tree and the information derived from § 381.603(a). CCP's shall be identified for purposes of product safety only. They must include physical, chemical, and biological (including microbiological and residue) hazards; must encompass the health and safety process control points required by FSIS regulations, or their equivalents; and must be specified for each identified hazard.

(c) *Principle No. 3.* Establish specific critical limits for preventive measures associated with each identified CCP. Critical limits which are a part of other portions of relevant regulations must be included.

(1) All critical limits shall meet or exceed any requirement set forth in this part pertaining to a specific process and which are currently a part of FSIS regulations or other FSIS requirements.

(2) The responsible establishment official shall ensure that the critical limits are sufficient to control the identified hazards through a validation process consisting of verification and monitoring activities.

(d) *Principle No. 4.* Establish CCP monitoring requirements. Establish specific procedures for using the results of CCP monitoring to adjust and maintain process control.

(1) The responsible establishment official shall ensure that establishment employees are assigned to monitor each CCP effectively, as determined by Hazard Analysis.

(2) When monitoring is not possible on a continuous basis, the monitoring interval established shall reliably indicate that the hazard can be controlled as demonstrated by process validation performed during the Hazard Analysis and plan development.

(3) All records and documents associated with CCP monitoring shall be dated and signed or initialed by the person(s) conducting the monitoring.

(e) *Principle No. 5.* Establish corrective action(s) to be taken when monitoring indicates that there is a deviation from an established critical limit.

(1) The corrective actions shall describe the step(s) taken to identify and correct the cause of noncompliance to assure that the CCP is under control, ensure that no safety hazards exist after these actions, and define measures to prevent recurrence.

(2) Corrective actions shall include a determination of the effect of the deviation(s) on product safety; how noncompliant product will be handled, including segregation and holding procedures; a definition of lot size; whether the deviation indicates a modification or revision of the HACCP plan is required; and time frames for modification or revision of the HACCP plan.

(f) *Principle No. 6.* Establish effective recordkeeping and systematic review procedures that document the HACCP system. The required records are specified in § 381.606.

(g) *Principle No. 7.* Establish procedures for verification by a HACCP-trained individual that the HACCP system is functioning effectively to ensure product safety and process control. This is the plan validation process and therefore includes methods, procedures, or tests in addition to those used for monitoring. Such validation shall ensure:

(1) The adequacy of the critical limits at each CCP;

(2) The continuing effectiveness of the establishment's HACCP plan and system, including taking into account changes in production volumes, procedures, personnel, and product use;

(3) The accuracy of the HACCP plan through the completion of all seven principles and their associated actions including revalidation whenever significant product, process, deviations, or packaging changes require modification of the plan; and

(4) The evaluation of product safety in situations where the establishment identifies deviations from critical limits, all steps taken in response to a deviation, and the adequacy of the corrective response.

§ 381.604 Implementation of the HACCP plan.

(a) Upon completion of the Hazard Analysis and development of the HACCP plan, a responsible establishment official shall review and approve the written plan by signing it.

(b) Upon completion of the Hazard Analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended, ensuring the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions. During this initial HACCP plan validation period, the establishment shall conduct repeated verifications and meet frequently with Program employees to assure the HACCP system is functioning as intended, which shall include a review of the records generated by the HACCP system.

(c) When an ingredient change, product reformulation, manufacturing process or procedure modification, equipment change, or any other such change requires modifications to the establishment's HACCP plan, the responsible establishment official, in consultation with a HACCP-trained individual employed by the establishment, shall ensure that the HACCP plan is modified to reflect such changes. The development of the modified HACCP plan shall be

conducted in accordance with §§ 381.602 and 381.603.

§ 381.605 Operation of HACCP system.

(a) The establishment's HACCP system, as set forth in the establishment's HACCP plan, shall be operated with the advice and guidance of a HACCP-trained individual as defined in § 381.601(i).

(b) The responsible establishment official shall be held responsible for the operation of the HACCP system to ensure compliance with the Act and regulations thereunder. In all respects, however, the Administrator shall continue to provide the Federal inspection necessary to carry out the provisions of the Act.

§ 381.606 Record review and maintenance.

(a) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the time recorded, and the record shall be signed or initialed by the establishment employee making the entry. Prior to shipping product produced under each process, the establishment shall review, on a defined, systematic basis, all processing and production records associated with the HACCP plan to ensure completeness, to determine whether all critical limits were met and, if appropriate, corrective action(s) were taken, including proper disposition of product. This review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by the HACCP-trained individual, or the responsible establishment official.

(b) The following records supporting the establishment's HACCP plan shall be maintained:

(1) The written HACCP plan including all portions of the Hazard Analysis as prescribed in this subpart;

(2) Records associated with the monitoring of CCP's, which include the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s) identity, or slaughter production lot; and date the record was made; and

(3) Records associated with supporting documentation for the Hazard Analysis, development of the selected CCP's, critical limits, frequency of monitoring and verification procedures, and corrective actions taken.

(c) All such records shall be made available to any Program employee upon request. Documents associated with a deviation from a critical limit shall be brought to the attention of the appropriate Program employee promptly.

(d) All records shall be retained at the establishment at all times, except that records for monitoring CCP's, corrective actions, and verification procedures shall be retained at the establishment for no less than 1 year, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees.

§ 381.607 Enforcement.

(a) *Implementation.* (1) The following establishments shall meet the requirements of this subpart by the date prescribed:

(i) Establishments that conduct the following categories of processes shall comply by [insert date 12 months after publication of final rule]: Raw, Ground (including mechanically separated poultry); Thermally Processed/ Commercially Sterile; and All Other, Shelf Stable, Heat Treated.

(ii) Establishments that conduct the following categories of processes shall comply by [insert date 18 months after publication of final rule]: Non-Shelf Stable, Heat Treated, Not Fully Cooked; and Shelf Stable, Not Heat Treated.

(iii) Establishments that conduct the following categories of processes shall comply by [insert date 24 months after publication of final rule]: Fully Cooked, Non-Shelf Stable; and Non-Shelf Stable with Secondary Inhibitors.

(iv) Establishments that have the following categories of processes shall meet the requirements of this part by [insert date 30 months after publication of final rule]: Raw, Other; and Slaughter, All Poultry Kind.

(v) Small entities that generate less than $2.5 million dollars of product per year shall comply by [insert date 36 months after publication of final rule].

(2) Any establishment that obtains Federal inspection on or after the effective date(s) for the process category(ies) to be conducted shall conduct a Hazard Analysis, and shall develop and validate its HACCP plan(s), as set forth in § 381.602(d) of this subpart, concurrent with the grant of inspection. Process analysis, as set forth in § 381.604(c), shall commence after obtaining Federal inspection to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(3) Any establishment that institutes a new process requiring development of a HACCP plan on or after the applicable effective date(s) of this regulation shall conduct all activities required for hazard analysis, development, and validation of its HACCP plan(s) for the process category(ies), as set forth in § 381.602(d) of this subpart, before commencing production and shall conduct process analyses, as set forth in § 381.604(b), to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(4) Commencing with the applicable effective date(s), the Program shall refuse new inspection services requested for, or, using the procedures in § 381.237, suspend inspection services from establishments or specific processes within establishments not having HACCP plans.

(b) *Verification.* The Program shall verify that HACCP plan(s) are effective and validated, and otherwise in compliance with this regulation. Such verification and process validation may include:

(1) Reviewing the HACCP plan,

(2) Reviewing the CCP records,

(3) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs,

(4) Conducting verification activities to determine whether CCP's are under control,

(5) Reviewing the critical limits,

(6) Reviewing other records pertaining to the HACCP plan or system,

(7) Random sample collection and analysis to determine the safety of the product, and/or

(8) On-site observations and records review for revalidation of HACCP plans.

(c) *Suspension, correction of invalid plans.* (1) If the Program finds a HACCP plan to be invalid, inspection service for the process covered by the HACCP plan will be suspended using the procedures in § 381.237. The processing facilities identified shall not be used for production of poultry product pending completion of the specified corrective action(s), as prescribed in paragraph (c)(3) of this section, and written acknowledgement thereof by the designated Program official. Product produced by that process prior to the suspension suspected of being adulterated shall be retained at the establishment pending disposition by the Program, and if such product has been shipped, it shall be subject to voluntary recall as necessary to protect public health.

(2) A HACCP plan may be found invalid if:

(i) The HACCP plan does not meet the requirements of this subpart,

(ii) HACCP records are not being maintained as required to validate the

plan or verify process control under the plan, or

(iii) A processing failure results in production of adulterated product.

(3) Invalid HACCP plans must be corrected by:

(i) Submission to the designated program official of a written, detailed verification by a HACCP-trained individual that a modified HACCP plan has been developed in consultation with that individual and that as modified the plan corrects the deficiencies found, and

(ii) In the case of a processing deficiency resulting in production of adulterated product, submission to the designated Program official of and adherence to a written plan for finished product produced under the modified HACCP plan to be tested by an external laboratory for chemical or microbial characteristics, at the establishment's expense, as appropriate to demonstrate that the process under the modified HACCP plan corrects the identified problem.

(4) If the establishment fails to adhere to the modified HACCP plan and, if applicable, the testing plan, resulting in a subsequent suspension of the same process for the same or a related deficiency, the designated Program official will, upon receipt and before acknowledgement of any subsequent modified plan(s) under paragraph (c)(3) of this section, also review the establishment's performance under the inspection regulations generally and make a written recommendation to the Administrator as to whether any additional inspection or enforcement measures may be required.

(5) If the Administrator finds deliberate falsification of HACCP records, the Administrator will issue a complaint for withdrawal of inspection services from the establishment and will refer the case to the Department of Justice for criminal prosecution.

Done at Washington, DC, on January 25, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

Note: The following Appendix will not appear in the Code of Federal Regulations.

Appendix—Generic HACCP for Raw Beef

National Advisory Committee on Microbiological Criteria for Foods

Adopted June 17, 1993

Table of Contents

I. Introduction

The following generic Hazard Analysis Critical Control Point (HACCP) plan for beef slaughter and processing focuses on the slaughter and processing portions of the total ''farm to consumption'' scope of a complete HACCP program. The Committee realizes that animal production practices can play a significant role in controlling microorganisms of food safety concern. An overview of key attributes of live animal management that significantly impact introduction or control of foodborne pathogens in relation to the ultimate microbiological safety of raw beef products is included in Section V.A. Likewise, specific practices and procedures are required to ensure the microbiological integrity of beef products while they are in distribution networks and during retailing. Improper handling of products during processing, distribution, in food service establishments or in the home, can result in the introduction, survival, or growth of pathogenic microorganisms. A lack of adequate controls throughout the complex food chain will increase the risk of foodborne disease. This portion of the total HACCP program is introduced in Section V.C, and will be additionally discussed in a more general document that will be developed to identify critical factors that must be controlled to ensure the safe distribution and marketing of meat and poultry products.

The generic HACCP plan reviews the processing steps of slaughter operations. The goal of HACCP for slaughter operations is to prevent, eliminate, or reduce both the incidence and levels of microorganisms pathogenic for humans. While beef slaughter operations do not include a lethal treatment (e.g., thermal process) that ensures elimination of pathogenic microorganisms, a number of the processing steps can be controlled to minimize microbiological hazards. The overall objective of the HACCP program is to ensure that processing is conducted in a manner that enhances the microbiological safety of the product. This is achieved through the effective management of key operations that can be used to realistically prevent or control the introduction or growth of pathogens.

Integral to HACCP systems is adherence to the general practices common to all well controlled food production facilities such as adequate sanitation, good manufacturing practices (GMPs), effective equipment/facility design, and maintenance (ICMSF, 1988; Druce, 1988). A knowledgeable, well trained workforce is essential in carrying out these practices. Important GMPs related to beef slaughter operations are outlined in ATTACHMENT A.

Several new technologies for beef slaughtering are in various stages of development, testing, and implementation. New technologies that are likely to become operational in the near future are included in the generic HACCP plan. A summary that discusses each of the new technologies and the anticipated benefits of implementation is included (Section VII). Areas where additional research is required are also discussed (Section VIII). Academic, government, and industry researchers should be encouraged to address these and related areas that provide new knowledge and technologies for enhancing the microbiological safety of beef products.

The generic plan provides general guidance for developing plant-specific plans. Such individualized HACCP plans for specific products and facilities should be developed and implemented by manufacturers as the optimal means for food safety management (NACMCF, 1992). HACCP is also recommended for use as a tool for inspection operations. The food processor has the responsibility for developing and implementing well-defined HACCP plans. The role of the regulatory agency is to verify that the processor's HACCP plans are effective and being followed. The USDA inspector should use the HACCP plan for monitoring and conducting verification as necessary. A discussion of the role of regulatory agencies and industry is included in Section VI.

In addition, a generic document which outlines the specific roles of the regulatory agencies and industry in HACCP has been prepared by a separate Working Group of the Committee.

The Committee recommends the adoption of HACCP principles to reduce

the risk of contamination by pathogenic microorganisms. In accordance with the NACMCF focus on safety (NACMCF, 1992), the current plan specifically addresses microbiological safety. However, it is worth noting that the increased process/product control achieved through the adoption of HACCP is also likely to enhance the microbiological quality of raw beef products. Full implementation is critical for HACCP plans to be successful. Management's commitment to the HACCP concept is imperative for successful implementation. The Committee recommends that HACCP plans include consideration of specific mechanisms for facilitating communication among all levels of plant operations and management.

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II. Epidemiology of Foodborne Illness Associated With Raw Beef

A. Introduction

Foodborne disease is an important cause of morbidity in the United States and throughout the world (Archer and Kvenberg, 1985; Cliver, 1987). Surveillance of foodborne diseases and prospective studies have identified foods of animal origin as important vehicles for microorganisms causing human illness (Todd, 1983, 1989; Bean and Griffin, 1990). The live animal is exposed to a variety of potential sources of microorganisms (e.g., soil, water, feeds, air, other animals, etc.), and often acquires pathogenic microorganisms initially as a result of exposure ''on the farm'' or during transport (Galton, et al., 1954; Ayers, 1955; Linton, et al., 1974; Martin and Smith, 1984; Clegg, et al., 1986; Grau, 1987; Linton and Hinton, 1987). In healthy animals, microorganisms are confined primarily to the gastrointestinal tract and exterior surfaces (hooves, hide, hair). During slaughtering and dressing, the surface of the carcass and subsequent cuts of meat may become contaminated with these microorganisms (Ayers, 1955; Mackey and Derrick, 1979; Smeltzer, 1984; Chandran, et al., 1986; Grau, 1987; Dixon, et al. 1991). Foods of animal origin may also be contaminated by microorganisms persisting in the processing environment, or as a result of contact with food handling personnel or equipment during processing, distribution, retailing, and use (Empey and Scott, 1939; Ingram, 1949; DeWit and Kampelmacher, 1981, 1982; Smeltzer, 1984; Smulders and Woolthuis, 1983; Druce, 1988; Ligugnana and Fung, 1990; Restaino and Wind, 1990). The extent of this contamination will depend, to a large degree, on the sanitary control exerted during slaughtering and dressing (Ayers, 1955; Empey and Scott, 1949; Ingram, 1949; Smulders and Woolthuis, 1983; Chandran, et al., 1986; Dixon, et al., 1991). This section focuses on the microorganisms that are the primary cause of morbidity and mortality associated with raw beef products.

B. Sources and Limitations of Data

In the United States, foodborne disease data are derived from outbreak investigations, prospective studies, and outbreak and sporadic disease surveillance conducted and reported by public health organizations such as the U.S. Centers for Disease Control and Prevention (CDC). The majority of the data is acquired through passive outbreak surveillance programs. It is assumed that the incidence data represent only a fraction of the total number of cases due to significant under reporting (Bean and Griffin, 1990; Buchanan and DeRoever, 1993). Such programs do not effectively record the incidence of sporadic disease. Assessing the impact of raw beef products on foodborne disease is complicated by the potential for such foods to serve as an indirect source of pathogens. Further, most available outbreak data are for cooked beef products. Identification of any relationship between an outbreak and the presence of pathogenic microorganisms in raw beef must be determined through adequate investigations that pinpoint food handling, processing, and preparation errors. Typically, microbial foodborne disease outbreaks involve errors associated with mishandling or inadequate processing of the raw beef, failure to control time and temperature after cooking, or post-processing contamination.

C. Outbreak Data

In the United States between 1973 and 1987, beef products accounted for 9% of reported outbreaks and 10% of the cases in which a food vehicle was implicated (Bean and Griffin, 1990). Similar results were reported for Canada (Todd, 1989). Raw beef has been reported to serve as a vehicle for a variety of disease causing organisms (i.e., viruses, protozoa, parasites, etc.); however, bacterial pathogens accounted for 92% (159 of 172) of beef-associated outbreaks in which an etiologic agent was identified (Bean and Griffin, 1990). The primary bacterial etiologic agents for beef-related outbreaks were *Salmonella* spp. (48%), *Clostridium perfringens* (32%), and *Staphylococcus aureuas* (14%). Recently, *Escherichia coli* 0157:H7 has played an increasingly important role as a cause of raw beef associated foodborne illness. Contamination of the raw beef combined with improper food handling practices is an important factor in a substantial portion of the *Salmonella* cases (Silliker, 1982; Bryan, 1979). *Clostridium perfringens* outbreaks are generally associated with cooked products that are held at inadequate holding temperatures in institutional and food service settings (Bryan, 1980). Spices and other dry ingredients can also be a source of *C. perfringens*, enterotoxigenic *Bacillus cereus*, *S. aureus*, and *Salmonella* (NRC, 1985). Food handling personnel are the primary source of *S. aureus*, and outbreaks are generally associated with temperature abuse after contamination of the cooked products (Bryan, 1980).

D. Sporadic Cases

Foodborne diseases that are predominately associated with sporadic cases are under-represented by outbreak data. A pertinent recent example associated with beef is *E. coli* 0157:H7, a major agent of hemorrhagic colitis (Belongia, et al., 1991; Doyle, 1991; Griffin, et al., 1988; Riley, 1987; Wells, et al., 1991). A prospective study of diarrheal disease in the State of Washington identified this organism as the third most frequently isolated cause of bacterial diarrheal disease (MacDonald, et al., 1988). Of particular concern is this organism's association with hemolytic uremic syndrome (HUS), a sequela of hemorrhagic colitis. This life-threatening, chronic kidney disease occurs in 2–7% of patients with shiga-like toxin *E. coli*-associated disease (Griffin and Tauxe, 1991). HUS has a 6% rate of mortality, with children being the most susceptible.

Listeria monocytogenes is another pathogen where a substantial portion of the cases caused by this microorganism are sporadic. While foodborne transmission appears to account for most human listeriosis cases, no epidemiological link to beef products

has been established (Schuchat, et al., 1991, 1992; Farber and Peterkin, 1991; Ryser and Marth, 1991).

E. Mechanisms of Transmission and Risk Factors

Since beef products may be eaten after cooking procedures that are insufficient to assure elimination of bacterial pathogens, intrinsic contamination of the raw product represents a potential risk. This is particularly true for ground beef where contamination that would normally be limited to the exterior of meat is spread throughout the product during grinding (ICMSF, 1980). This problem has also occurred when roast beef that was internally contaminated by restructuring or injection was inadequately cooked (Bryan and McKinley, 1979).

Food handling errors often contribute to foodborne disease outbreaks (Todd, 1983, 1989). These include such factors as improper holding temperatures, inadequate cooking, contaminated equipment, and food handler hygiene. Inadequate cooking and improper holding temperatures are particularly pertinent for beef products. A number of these factors have been addressed successfully. For example, undercooking in commercial plants has been addressed through the standardization of thermal processing requirements, such as the guidelines for roast beef (USDA, 1983 NACMCF, 1989). However, similar levels of control have not been achieved in the home or in all food service establishments.

Other factors that appear to influence the incidence of foodborne disease are the source, primary purpose, and health of the animals. At least for *E. coli* 0157:H7, there is a strong correlation with meat from dairy cattle, but not ''fed'' cattle (Wells, et al., 1991; Doyle, 1991; Griffin and Tauxe, 1991). The incidence was highest in young animals. Higher incidences of *Salmonella* contamination of raw beef products also appears to be correlated with calf slaughter operations (Hogue, et al., 1993).

The beef industry is made up of two major segments. Animals for the fed-cattle market come through feedlots to the slaughter plants. These are largely animals raised for higher quality meat, and are processed into wholesale cuts for boxed beef. The trimmings go into manufacturing ground beef or sausage. The majority of fed-cattle are slaughtered by a small number of large operators. Cow meat is produced from culled dairy cattle or beef cows advanced in age. The primary use of cow meat is ground beef and processed meats. This segment of the industry is characterized by a large number of small operators. A recent survey of the beef slaughter industry indicated that the overall microbiological quality of raw beef was inversely correlated to slaughter volume; however, no such association was observed for *Salmonella* contamination (Hogue, et al., 1993). *Salmonella* contamination was more closely related to the health of animals brought to slaughter. It is important to note that surveys of this type only provide broad statistical trends. Further work is needed to determine the operational differences both within and between large and small volume operations that could account for the observed trends.

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III. Microbiological Profile of Raw Beef

A. General Microbiological Parameters Associated with Beef

Beef muscle is a nutrient-rich substrate that can support the growth of a wide range of microorganisms. It is generally assumed that the interior of intact muscle is free of microorganisms. However, localized presence of bacteria can occur in lymph nodes or the area adjacent to bone joints, particularly if they are inflamed. Microorganisms are introduced into the interior of meats as a result of the translocation of bacteria from the surface of the carcass. The initial microflora is diverse at the time of slaughter; however, subsequent refrigerated storage selects for a limited group of aerobic psychrotrophic species, particularly those of the *Pseudomonas-Moraxella-Acinetobacter* group (Johnston and Tompkin, 1992). The specific genera encountered is dependent on the storage temperature, oxygen availability, pH, and moisture content (von Holy and Holzapfel, 1988).

1. Temperature

Microbial growth in beef is strongly dependent on environmental temperature. As storage temperatures are lowered toward freezing there is a significant decrease in the rate of microbial growth as well as a reduction in the diversity of the microflora.

2. Moisture Content

Fresh meat has a water activity (a_w) of ≥0.99 which supports the growth of a wide variety of bacteria, yeast, and molds. At high a_w values (a_w >0.97), the rapid growth rates characteristic of bacteria allow them to predominate. However, as meat surfaces dry, the differential in growth rates becomes less important. Below a_w values of 0.94, fungal species play an increasingly important role as the dominant type of microorganism.

3. pH

The pH of fresh beef is dependent on a number of factors including feeding and handling practices at the time of slaughter, and range from 5.3–6.5. Under normal conditions, the pH of beef after slaughter and chilling is ≤5.8. Both the rate of microbial growth and the diversity of the microflora will be restricted at the lower end of the pH range (Grau, 1981).

4. Oxygen Availability

Unpackaged fresh beef actually represents two microbiological environments in relation to oxygen availability. The surface is aerobic; an environment that permits the rapid growth of aerobic psychrotrophs such as *Pseudomonas*. However, the poising capacity of meat tissue is high, and an anaerobic environment predominates within 2 mm of the surface. This selects for anaerobes, microaerophiles, and facultative anaerobes. Restricting oxygen availability through the use of physical barriers can substantially alter microbial growth at the surface of meats. Fresh beef is an actively respiring system and even a partial restriction of oxygen permeability across a plastic wrap results in a depletion of oxygen and an accompanying increase in carbon dioxide. This produces a shift from aerobic species (e.g., pseudomonads) to microaerophiles and facultative anaerobes such as *Lactobacillus, Pediococcus, Leuconostoc, Streptococcus, Carnobacterium*, and *Brochothrix*. Grinding raw beef increases the surface area exposed to oxygen, at the same time distributing any contamination present on the surface throughout the meat. However, the increased surface area also increases the amount of actively respiring muscle tissue, leading to rapid oxygen depletion within packaging material that restricts oxygen availability.

There has been speculation that vacuum packaging or modified atmosphere packaging (VP/MAP) could lead to a situation where if a product

was temperature abused, the normal aerobic spoilage microflora could be suppressed, but pathogenic facultative anaerobes would grow unabated (Genigeorgis, 1985; Hintlian and Hotchkiss, 1986; Gill and DeLacy, 1991). At present, there is little epidemiological or other data available indicating that there are any problems with VP/MAP of raw beef. However, the potential must be considered when evaluating the hazards associated with beef.

B. Potential for Foodborne Pathogens

Low levels of pathogenic bacteria can be isolated from a varying percentage of raw beef products. A number of studies have examined raw beef products for *L. monocytogenes* worldwide, with reported incidence rates ranging from 0 to >50% (Ryser and Marth, 1991). The incidence rates for *Salmonella* on raw beef are generally low (<5%); however, higher rates have been reported (Felsenfeld, et al., 1950; Weissman and Carpenter, 1969; Goo, et al., 1973; Nazer and Osborne, 1976; Stolle, 1981). The incidence of *E. coli* 0157:H7 in raw beef appears to be low, and associated with dairy cattle (Doyle and Schoeni, 1987; Belongia, et al., 1991; Wells, et al., 1991).

The sources of pathogenic microorganisms vary. For example, *S. aureus* is generally associated with food handlers or mastitic cows. *Salmonella, E. coli*, and other enteric pathogens are typically associated with fecal material and can be commonly isolated from the hooves and hides of cattle (Stolle, 1981). There appear to be several means by which enteric pathogens become attached to raw beef, though there does appear to be a preferential binding to connective tissue (Benedict, et al., 1991). Recent research has indicated that the preferential binding of *Salmonella* to connective tissue involves a genetically encoded cell surface binding site (Sanderson, et al., 1991). *L. monocytogenes* can be endemic in cattle; however, recent European studies (Ryser and Marth, 1991) suggest that the food processing environment can be an important source of this pathogen. The presence of low levels of pathogenic bacteria on beef may be unavoidable; however, care must be exercised to ensure that this level is minimal. Further, beef products should be handled in a manner that assures that pathogens of significance have little or no opportunity to proliferate (Gill and DeLacy, 1991).

A variety of mesophilic foodborne pathogens are potentially capable of growing in the microbiological environment associated with both the surface or the interior if the meat is held above 8–10°C (Mackey, et al., 1980; Grau, 1981; Gibson and Roberts, 1986; Smith, 1987). The microflora of raw beef may contain members that competitively inhibit the growth of enteric pathogens such as *Salmonella* under certain conditions (Gilliland and Speck, 1977; Gill and Newton, 1980). However, a number of studies have concluded that the microflora of raw beef cannot be relied on to prevent the growth of mesophilic pathogens in temperature-abused beef (Mackey, et al., 1980; Smith, 1985, 1987; Mackey and Kerridge, 1988). Further, vacuum and modified atmosphere packaged raw beef that is temperature abused at ≥12°C and ≥15°C may support significant growth of *Salmonella* before overt spoilage is detected (Gill and DeLacy, 1991). Initial studies on the growth characteristics of *E. coli* 0157:H7 (Buchanan and Klawitter, 1992c; Glass, et al., 1992) indicate that it is likely to behave in a manner similar to other serotypes of *E. coli* and *Salmonella* (Smith, 1985, 1987; Hughes and McDermott, 1989).

Psychrotrophic pathogenic species, including *L. monocytogenes*, *Yersinia enterocolitica*, *Aeromonas hydrophila*, and some strains of *Bacillus cereus*, represent a special concern because they are capable of growth at refrigeration temperatures. While both *Y. enterocolitica* and *B. cereus* have been epidemiologically linked to products of animal origin, typically they are not associated with raw beef products. *Aeromonas hydrophila* can be frequently isolated from refrigerated raw beef; however, the role of this organism in disease outbreaks involving non-immunocompromised individuals is still poorly understood (Palumbo, et al., 1991).

While there have been no outbreaks of listeriosis attributed to raw beef products, *L. monocytogenes*' growth characteristics, increased thermal resistance compared to enteric pathogens, and incidence in raw and cooked meat products (Ryser and Marth, 1991) has prompted investigations of its behavior in raw beef. *Listeria monocytogenes* is capable of growth in temperature-abused raw beef (Buchanan and Klawitter, 1992a); however, there are conflicting reports concerning the ability of the organism to grow in raw beef at ≥5°C (Kahn, et al., 1972; 1973: Johnson, et al., 1988a, b; Grau and Vanderlinde, 1988; Buchanan, et al., 1989; Gill and Reichel, 1989; Glass and Doyle, 1989; Shelef, 1989; Dickson, 1990; Buchanan and Klawitter, 1991; Kaya and Schmidt, 1989, 1991). The observed differences may be attributable to either the pH (Gill and Reichel, 1989; Kaya and Schmidt, 1991) or the physical form (cuts versus ground) (Buchanan and Klawitter, 1991) of the meat. The effects of individual microorganisms of meat microflora on the growth of *L. monocytogenes* include none, inhibitory, and even stimulatory, depending on the specific species or strain (Ingram, et al., 1990; Tran, et al., 1990; Mattila-Sandholm and Skytta, 1991). A number of raw meat isolates of lactic acid bacteria, particularly *Carnobacterium* and *Lactobacillus* species, have been reported to produce bacteriocins against *L. monocytogenes* (Schillinger and Lucke, 1989; Ahn and Stiles, 1990a, b; Mortvedt and Nes, 1990; Lewus, et al., 1991; Buchanan and Klawitter, 1992a, b). While there are potential applications for controlling foodborne pathogens through the use of a competitive microflora (Buchanan and Klawitter, 1992b), the current state of knowledge does not allow this to be relied on as a primary means of control. The primary means for controlling psychrotrophic pathogen growth remains the maintenance of storage temperatures as low as possible (≤2°C) and a normal low pH (<5.8).

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IV. Hazard Analysis

Epidemiological data (section II. A–E) indicate that three microorganisms have accounted for 94% of the outbreaks in which beef has been implicated. Raw beef has been a major source for salmonellae in the outbreaks. Raw beef has been one of many potential sources

for *C. perfringens*. Raw beef can be a source of *S. aureus*. This is a concern in the manufacture of fermented and dried meats. Raw beef is a source for sporadic cases and, occasionally, outbreaks of illness due to *E. coli* 0157:H7.

The hazard analysis leads to the conclusion that raw beef can be an important vehicle in the transmission of two important foodborne pathogens: salmonellae and *E. coli* 0157:H7. These pathogens are similar in a number of respects, such as:

a. Sensitivity to heat and cold,

b. Sensitivity to chemicals,

c. The ability to multiply asymptomatically in the bovine intestinal tract, and

d. Potential for low infectious doses.

E. coli 0157:H7 and certain *Salmonella* serovars may cause secondary infections and chronic sequelae. Also, both pathogens may cause death, particularly with *E. coli* 0157:H7.

The primary microbiological hazards encountered during the beef slaughtering process are salmonellae and *E. coli* 0157:H7. The following generic HACCP plan will be directed primarily at control of these pathogens. Efforts to improve slaughter hygiene will reduce the presence of other pathogens (*C. perfringens, S. aureus, L. monocytogenes*) on carcass meat.

V. Generic HACCP

The factors that impact the microbiological safety of raw beef products during its ''farm to consumer'' lifetime can be subdivided into four segments: (1) live animal practices, (2) slaughter and processing operations, (3) distribution and retailing operations, and (4) consumer food handling practices. Key factors associated with live animal practices are introduced and discussed in Section V.A. The individual steps involved in slaughter and processing operations are detailed as a generic HACCP plan in Section V.B. The primary thrust of the first two sections is the control of enteric bacteria, the class of pathogenic microorganisms associated with and amenable to control during these phases of raw beef production and processing. The factors associated with distribution, retailing, and consumer practices that impact the safety of raw beef products are introduced in Section V.C.

A. Farm Management Practices

Raw beef originates from several sources of cattle. These can be classified into two major categories, fed beef and mature beef. Fed beef typically comes from animals that have been raised to desired market weight, usually less than two years of age. Mature beef comes from dairy or beef animals that have been marketed after being used for milk or calf production. Fed beef serves as the major source of whole beef products and some ground beef products. Mature dairy and beef animals are a primary source of ground meat and patties to consumers, including food service establishments.

The husbandry practices under which fed beef cattle and mature dairy and beef cattle are managed are quite different. However, potential for microbial contamination of the final product exists in both and they share many of the same risks. There are major aspects in the production phase that can influence incidence, control, and prevention of potential human pathogens in cattle.

1. Transportation

The production cycle, especially of fed beef, typically involves time spent on two or more premises prior to movement to processing facilities. Transportation is often necessary but contributes to an increased incidence of contamination due to both the stress placed upon animals and the increased risk of exposure of cattle to potential human pathogens (Cole, et al., 1988; Hutcheson and Cole, 1986). Dairy animals handled in a similar manner would experience similar risk.

Transport time should be such that the animals reach other production facilities and processing establishments in an expedient manner, with stress kept to a minimum. Transport vehicles should be free of injurious structural defects. Vehicles should be clean at the time animals are loaded, and cleaned and sanitized following unloading at the slaughter facility.

2. Marketing

Marketing is accomplished through a number of outlets that introduce varying degrees of risk. Cattle frequently are sold or moved through either auction markets, direct selling from producer to backgrounder or feedlot, video auctions, or collection points. Animals from multiple sources are commonly commingled at one or more points during production, resulting in transfer of potential pathogens between animals.

Inspectors at slaughter plants must maintain high standards regarding diseased and otherwise inferior animals, including continued close communication with cattle producers to provide information to improve quality and safety standards in slaughter animals.

3. Animal Husbandry

Numerous management practices are influenced by environmental conditions. For example, excessive moisture conditions generally result in higher levels of hide contamination with mud, feces, and other extraneous matter. Management systems that minimize the impact of adverse environmental conditions would be expected to decrease microbial contamination. This may involve basic changes in animal husbandry (Smith and House, 1992). Controlling exposure and contamination is especially important immediately prior to shipment to slaughter.

4. Role of Stress

Stressed animals have lowered disease resistance, making them more susceptible to pathogens and at increased risk of shedding potential human pathogens (Breazile, 1988). For example, animals which are exposed to salmonellae can become intermittent shedders of this organism. Various forms of stress can result in increased shedding and clinical disease, causing increased exposure to pennates, increasing the risk also to humans through contaminated meat.

Management systems addressing increased animal welfare and better husbandry decrease levels of stress, and would be expected to decrease the incidence of pathogens. For example, improvements in cattle handling systems reduce stress-related immune suppression associated with animal processing procedures (Grandin, 1984, 1987). A number of other factors, such as animal density, frequency of feedlot pen use, and commingling of sick animals, can affect stress levels and thus risk of human pathogen exposure. *Salmonella* is capable of surviving variable, prolonged periods of time in animal facilities (Rings, 1985).

5. Feed and Water Contamination

Feed and water are potential sources of microbial contamination to cattle (Robinson, et al., 1991). Feedstuffs should be documented free of *Salmonella* and other enteric pathogens (Mitchel and McChesney, 1991). This is especially critical for feeds containing rendered byproducts. Water must be from clean, non-fecally contaminated sources.

6. Antimicrobial Use

Therapeutic and subtherapeutic use of antimicrobials has long been a practice in the cattle industry. Recent emphasis on regulations and resulting industry response, such as quality assurance programs, has resulted in more

responsible use of antibiotics in cattle. Therapeutic use of antibiotics is used to reduce effects of clinical diseases in cattle, including potential human pathogens such as salmonellae. Additional information is needed regarding advisability of some currently accepted practices, especially when considering human health risks (Rings, 1985; Kennedy and Hibbs, 1993).

7. Animal Identification

The beef and dairy industries, along with state and federal agencies, must continue to develop adequate means to identify animals from the initial production unit through the slaughter process. Permanent animal identification is essential so producers can assume further responsibility for the beef they market by being able to track animals through the entire production, slaughter, wholesale, and retail processes. Currently, mature animals are identified by backtags as part of the Brucellosis eradication program. Retention of this portion of the program is suggested until better means of identification are implemented. Permanent identification is a critical issue for improving the safety of raw beef at the producer level.

Projected Needs: Current and future strategies that may be useful in decreasing the risk of microbial contamination at production levels include assessments of the prevalence of human pathogens in cattle, permanent identification of animals using advanced technology (USAHA, 1992; Maher 1991; Nelson, 1991), use of new and improved vaccines, use of improved management methods in reducing microbial contamination risk, and incorporation of biotechnological advances in cattle production as they are proven to be beneficial in minimizing or preventing microbial contamination.

Producers should be encouraged to carefully review production methods and HACCP guidelines to decrease risks associated with pathogenic microbial contamination (Smith and House, 1992). Utilization of quality management principals is recommended since these concepts will result in improved quality assurance and pre-harvest food safety programs (Schmitz, 1993; FAPMC, 1992; AVMA, 1992). Implementation of production practices suggested by these programs are critical at all phases of cattle production regardless of unit size or type.

B. Slaughter Operations

Unit operations associated with the slaughter and dressing of beef are summarized in Figure 1. A more detailed examination of each of the steps is provided in ATTACHMENT D.

A CCP within a Hazard Analysis and Critical Control Point (HACCP) program is defined as any point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels (NACMCF, 1992).

Seven specific CCP process steps have been designated in the processing of raw beef (Figure 1 and Table 1). These include (1) skinning, (2) post-skinning wash/bactericidal rinse, (3) evisceration, (4) final wash/bactericidal rinse, (5) chill, (6) refrigerated storage, and (7) labeling.

For each of these CCP steps critical limits are defined for proper control. These CCPs must be monitored at a frequency sufficient to ensure process control. Corrective actions to be taken when CCPs do not meet critical limits should be specified clearly in the HACCP plan. This should include the priorities of actions to be taken and the individuals to be notified of the deviation. The HACCP system should be verified according to HACCP principle #7 (NACMCF, 1992).

The seven CCPs with procedures associated with the processing step are shown in the following outline.

Implementation and Management of HACCP Critical Control Points

CCP 1: Skinning

The hide is the first major source of microbial contamination on fresh beef carcasses. Cattle leaving the farm, feed lot, or sales barn for delivery to the slaughter plant, carry with them microbial populations indicative of what occurred during the care and handling of the live animal. *Salmonella* and other types of bacteria can be spread during the skinning process through contact with hide, hands and various pieces of equipment (Empey and Scott, 1939; Newton, et al., 1978; Stolle, 1981; Grau, 1987). Current skinning technology does not provide a means for destroying enteric pathogens that reside on the hide of animals coming to slaughter. There also is no available means to remove all soil from the hide of animals prior to slaughter; however, preslaughter washing does have a positive effect (Empey and Scott, 1939; Dixon, et al., 1991). Skinning, therefore, should be done in a manner that will minimize cross-contamination from the hide to the carcass. This contamination can be minimized by pulling the hide down and out from the carcass as opposed to upward and away. In addition, equipment and carcass contact surfaces must be properly cleaned and sanitized. The operator performing the skinning process must be trained to minimize contamination. Management must reinforce the proper techniques through adequate supervision.

The effectiveness of the CCPs outlined in this document are based on the concept of additive impact. Wash and bactericidal rinse steps will significantly reduce the level of microbial contamination resulting from the skinning or evisceration steps; however, the efficacy of these processes are dependent on control of skinning and evisceration. The procedures and corrective actions outlined for CCP 1 and CCP 3 minimize the level of contaminating material that must be removed by the wash and rinse steps.

If critical limits for CCP 1 are exceeded, corrective actions must be taken prior to the carcasses being subjected to the post-skinning wash and bactericidal rinse. Corrections of CCP 1 deviations can be achieved by adding additional operators to the skinning procedure, reducing the chain speed in the skinning area, and/or conducting carcass trimming prior to the post-skinning wash and bactericidal rinse.

CCP 2: Post-Skinning Wash and Bactericidal Rinse

During the skinning process, newly exposed carcass surfaces can become contaminated with dressing defects, i.e., fecal material, hide and/or dirt, that may introduce bacterial pathogens. A post-skinning wash and bactericidal rinse is an effective means of reducing this contamination. Any pathologic conditions, i.e., abscesses, septic bruises, etc., should be removed prior to CCP 2.

Maximum benefit of post-skinning wash and bactericidal rinse can be achieved if the amount of contaminating material is minimized, emphasizing the importance of CCP 1 (skinning). Proper skinning procedures must be achieved for effective post-skinning wash and bactericidal rinse.

Post-skinning wash and bactericidal rinse should occur as soon after skinning as possible to limit irreversible attachment of pathogens to the carcass. An in-line, post-skinning, potable water wash at 90–100°F and a pressure of 345–2070 kPa (50–300 psi) removes much of the visible surface contamination (hair, specks) and reduces microbial contamination to some extent (DeZuniga, et al., 1991). The water wash should be followed immediately by a bactericidal rinse to provide an effective reduction of surface bacteria. The bactericidal rinse should be an approved antimicrobial agent such

as chlorine (50 mg/L) or an organic acid (1–2% acetic, lactic, or citric acids) at a temperature of 120–140°F and a pressure of 70–275 kPa (10–40 psi) (Prasai, et al., 1991). Monitoring of this CCP should be conducted by continuous confirmation of concentration, temperature, pressure, and chain speed.

Validation of CCP 2 should be accomplished by microbiological testing of carcasses before and after CCP 2. A reasonable level of testing should be performed at the initiation of a HACCP program to establish baselines for total aerobic, mesophilic bacteria and/or *Enterobacteriaceae*. These microbiological indices are useful indicators of process control and overall sanitation, but are not effective as indicators of enteric pathogens. All testing should be performed using standard methods (Vanderzant and Splittstoesser, 1992). After establishment of the baseline, verification of CCP 2 can be achieved by periodic sampling of carcasses for the two microbiological indicators, using the same methods employed in establishing the baseline. These data should be reviewed using trend analysis and statistically significant increases should prompt a review of CCP 2 operations. Literature indicates a functioning wash and bactericidal rinse step in conjunction with acceptable adherence to CCP 1 should deliver an approximate 90% reduction in microbial levels. Specific bactericidal agent concentrations, temperatures, and pressures to be used should be based on appropriate available literature and in-plant testing to obtain optimal bacterial reductions (Patterson, 1968, 1969; Kotula, et al., 1974; Emswiler, et al., 1976; Quartey-Papafio, et al., 1980; Osthold, et al., 1984; Woolthuis and Smulders, 1985; Acuff, et al., 1987; Prasai, et al., 1991; and Dickson and Anderson 1992).

CCP 3: Evisceration

The intestinal tract is the second major source of enteric pathogens during the slaughtering process. Although the animals may be asymptomatic, they can still harbor large populations of enteric pathogens in their intestinal tract. The bunging and evisceration operators must be properly trained in removing the intestinal tract intact to successfully adhere to the control parameters of CCP 3. It is essential that the viscera not be accidentally cut and the contents contaminate the carcass, the operator, or equipment (Empey and Scott, 1939; Mackey and Derrick, 1979; Eustace, 1981; Smeltzer and Thomas, 1981; Grau, 1987). When the intestines are accidentally cut and contamination occurs, immediate sanitizing of equipment and knives should be performed with 180°F water, and involved personnel should utilize hand washing and sanitizing facilities to avoid contamination of subsequent carcasses. The most effective means of control lies in adequate training of the operator in the correct procedures, including providing the rationale on the importance of maintaining the viscera intact, coupled with positive reinforcement through appropriate supervision. Accordingly, monitoring this CCP entails periodic observation of the evisceration operations including visual inspection of eviscerated carcasses. This can correlate to potential carcass contamination.

CCP 4: Carcass Final Wash

Additional microbial contamination of the carcass surface is likely to occur as a result of evisceration, viscera handling, and carcass splitting. An in-line, potable water wash at 90–100°F and a pressure of 345–2070 kPa (50–300 psi) will help reduce microbial levels, including enteric pathogens (DeZuniga, et al., 1991). This final water wash should be followed by a bactericidal rinse containing an approved antimicrobial agent such as chlorine (50 mg/L) or an organic acid (e.g., 1–2% acetic, lactic, or citric acids) at a temperature of 120–140°F and a pressure of 70–275 kPa (10–40 psi) (Prasai, et al., 1991).

This combination of a final wash and bactericidal rinse will help minimize carriage of pathogens through the remaining beef fabrication and packaging processes. Monitoring of this CCP should be through continuous confirmation of antimicrobial concentration, temperature, pressure, and chain speed. Verification can be achieved by conducting microbiological testing as described in CCP 2 to confirm that CCP 4 is providing the anticipated level of control of microbial levels. Maximum effectiveness of CCP 4 can only be realized if the critical limits for CCP 1–3 are maintained. Any deviations associated with the earlier CCPs must be corrected before the product is subjected to the final wash. Specific bactericidal agent concentrations, temperatures, and pressures to be used should be based on appropriate available literature and in-plant testing to obtain optimal bacterial reductions (Patterson, 1968, 1969; Kotula, et al., 1974; Emswiler, et al., 1976; Quartey-Papafio, et al., 1980; Osthold, et al., 1984; Snijders, et al., 1985; Woolthuis and Smulders, 1985; Smulders, et al., 1986; Acuff, et al., 1987; Prasai, et al., 1991; and Dickson and Anderson 1992; Siragusa and Dickson, 1992; Dickson, 1992).

CCP 5: Chill

The bacterial flora including any enteric pathogens found on the sides of fresh beef could multiply if the meat is not properly chilled. Cooling rates must be sufficient to limit the growth of enteric pathogens. Temperature guidelines would include a deep muscle (6 in.) temperature of ≤ 45°F within 36 hours, with a temperature of ≤ 50°F reached within the first 24 hours (Reuter, 1990). Overnight rapid chilling of properly spaced beef sides is a proven system to control the multiplication of enteric pathogens (Grau, 1987; Mackey, et al., 1980). The CCP can be monitored through the continuous confirmation of physical factors affecting cooling rates such as environmental temperatures and air circulation rates. Verification can be achieved through the periodic recording of deep muscle cooling rates for selected carcasses, using appropriately calibrated temperature recording devices (e.g. thermocouple).

CCP 6: Refrigerated Storage

After chilling, the carcasses and resulting raw products must be maintained under adequate refrigeration during all subsequent handling and processing until the final product is ultimately consumed. This highly diffuse CCP requires that manufacturers, distributors, retailers, food service operators, and consumers each take responsibility for assuring that raw beef products are kept under adequate refrigeration. Maintaining products in a refrigerated state (product temperature ≤45°F), along with appropriate cleaning and sanitizing of equipment and food contact surfaces, will control the multiplication or accumulation of non-psychrotrophic pathogens. Further, maintaining storage temperatures as close to freezing as practical will enhance control of psychrotrophic pathogens.

CCP 7: Labeling

Adequate product identification (e.g., code dates, lot identification) is necessary for product control in the event that product must be traced or retrieved. To facilitate the responsibilities of distributors, retailers, food service operators and consumers, all raw and partially cooked beef products should be labeled to indicate that the product must be refrigerated, handled, and cooked properly to ensure safety. Methods of cooking and sanitary handling should reflect the needs of the specific product. Labels should be appropriate for either retail and

institutional consumers. A universal logo should be designed to identify raw beef products for consumers. The logo should include space for instructional information specific for the product. An example of a potential logo is depicted in Figure 2.

The seven CCPs are summarized in Table 1.

C. Distribution, Retailing, and Preparation

An effective HACCP plan for the production, slaughtering, and initial processing of raw beef will greatly increase control of pathogenic microorganisms; however, even under the best operating conditions low numbers of pathogens may remain on the carcass. Further, care must be exercised to prevent re-introduction of pathogens, such as *Salmonella* and *S. aureus*, that are epidemiologically linked to beef products.

After slaughter, dressing and processing, raw beef goes through a complex system of distribution and marketing (including wholesalers, distributors, retail stores and food service establishments) before ultimately reaching the end users who consume the products. Throughout distribution and preparation of raw meats, there is a significant potential for product mishandling leading to the introduction of additional pathogenic microorganisms, or the spread of any pathogens remaining on raw beef to other foods. Improper handling and storage practices, including improper holding temperatures, inadequate cooking, contaminated equipment and food worker hygiene, have all contributed to beef associated foodborne outbreaks (Bryan, 1988). The microbiological hazards associated with raw beef can be controlled by extending HACCP principles to product handling activities in retail stores, food service establishments, institutional feeding facilities, and homes.

The goal of the HACCP system in food distribution and preparation is to minimize microbial contamination, reduce the opportunities for pathogens that may be present to multiply, assure the destruction of pathogenic microorganisms through proper cooking procedures, and prevent the cross-contamination of pathogens from raw to cooked foods.

HACCP properly applied to all segments of distribution and preparation has the potential for:

1. Reducing the opportunities for pathogen growth, thereby reducing the risk of foodborne disease;

2. Assuring the destruction of enteric and other non-spore forming pathogens through proper cooking procedures;

3. Preventing the reintroduction of pathogens to the cooked product and cross-contamination of other foods; and

4. Controlling the growth of spore forming pathogens (e.g., *C. perfringens*) by use of proper time/temperature relations for storage, holding, and serving.

An effective HACCP system in food distribution and preparation depends on a general understanding of and adherence to the principles of sanitation, good manufacturing and food preparation practices as well as proper facility layout and equipment design and maintenance (See Attachment A). The education and training of all personnel is critical to the process and effectiveness of any HACCP program.

HACCP plans for handling and processing raw beef should be developed and implemented by food retailers and food service establishments as the optimal system for food safety assurance. In institutional feeding operations such as hospitals, nursing homes, day care centers, and prisons where the populations may be more vulnerable to foodborne disease, special care must be taken in the preparation of all foods, including raw beef products . The Committee recommends that HACCP systems be implemented immediately by food service establishments and institutions preparing foods for these special groups with increased susceptibility. General guidelines for the safe handling of raw beef in retail food stores and food service establishments are provided in Attachment B.

Several national surveys (Weimer and Jones, 1977; Williamson, et al., 1992) have shown that the public has a limited understanding of the basic principles of food microbiology and safe home food handling and preparation practices. In households, the successful use of HACCP principles is dependent on the interest, knowledge and skills of the food preparer. General guidelines for the safe handling of raw beef by consumers are provided in Attachment C.

D. HACCP Records and Verification

The acquisition and maintenance of records are an integral and critical principle of HACCP (NACMCF, 1992). Records of CCP performance along with documentation of related verification activities and process deviations are the primary tool by which a HACCP operation is managed and decisions are reached concerning the efficacy of process. The records of designated objective and subjective observations that should be maintained must be specified in the HACCP plan and maintained at the processing location. All records should be reviewed and integrated on a specified, routine basis. This should include subjecting the data to trend analysis to identify and correct problems before they result in CCPs exceeding critical limits. It is recommended strongly that this review be integrated, and the results communicated to both employees and supervisory personnel. The mechanism and duration of records maintenance is the responsibility of plant management, and should be specified in the HACCP plan. However, any system established must take into account the primary role that records review plays in verifications by regulatory agencies.

Establishing procedures for verification that the HACCP system is working correctly is an integral element in developing an effective HACCP plan and system. The verification procedures should:

1. Verify that the critical limits for CCPs are satisfactory,

2. Ensure that the facility's HACCP plan is functioning effectively,

3. Consist of documented revalidations, audits, or other verification procedures to ensure the accuracy of the HACCP plan, and

4. Provide regulatory verification that the HACCP system is functioning satisfactorily.

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TABLE 1.—GENERIC HACCP PLAN CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION

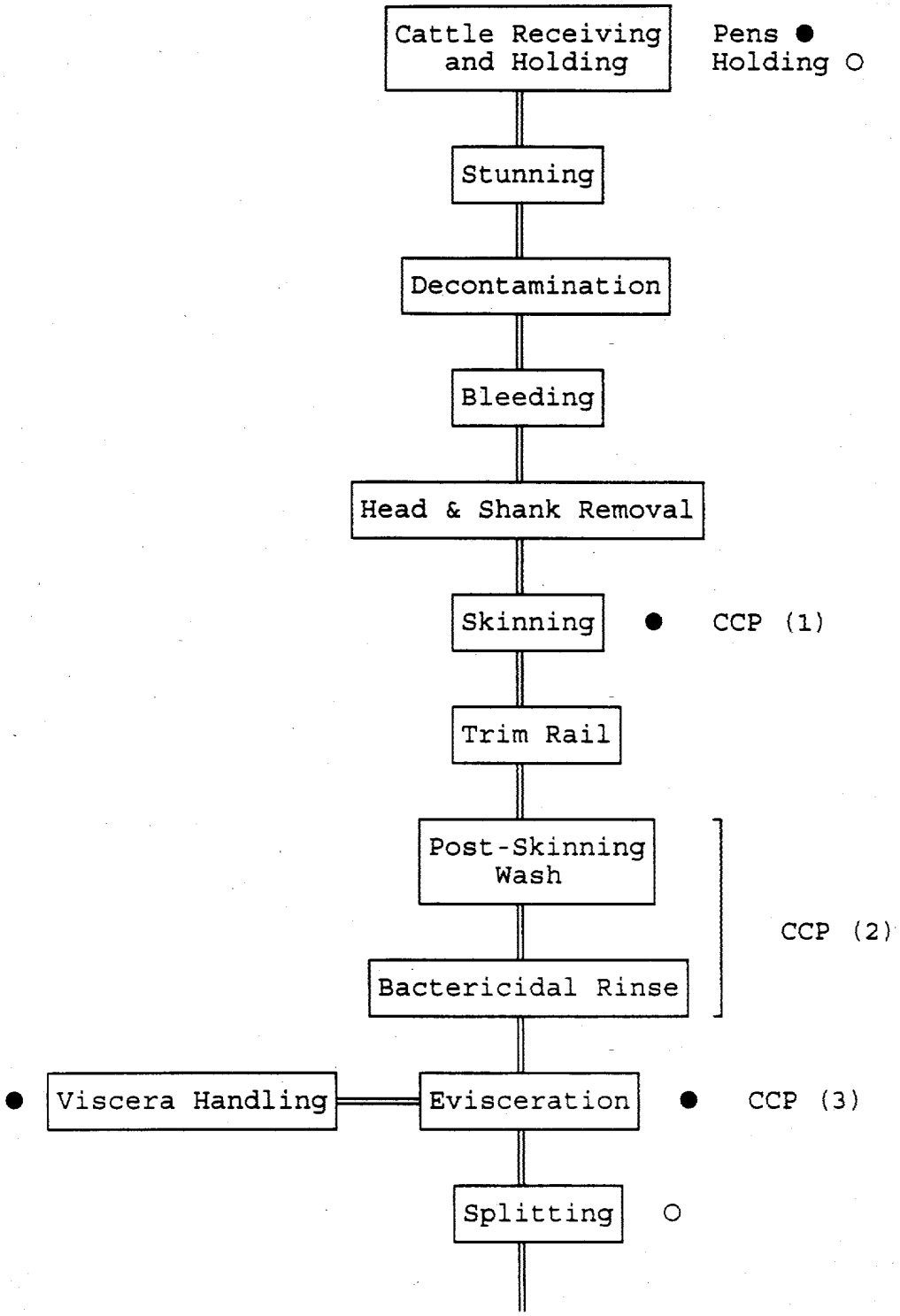
Process/step	CCP	Critical limits	Monitoring procedure/frequency	Corrective action	Records	Verification
Skinning	CCP(1) ...	≤20% of carcasses with dressing defects.	Operator observes effectiveness of skinning process for each carcass. Visual analysis should be conducted under adequate lighting per USDA requirements.	Add operators ... Reduce chain speed. Conduct carcass trimming.	Random post-skinning carcass examination log.	Examination of random carcasses after skinning is complete using sampling plan sufficient to assure process control. Supervisory review of records. Initially, conduct microbiological analyses for aerobic mesophiles and/or *Enterobacteriaceae* to establish baseline data on expected bacterial numbers. Periodic follow-up analyses and trend analysis to verify process control. Review control charts to confirm that sampling frequency is sufficient to detect 20% defect criteria.
Post-skinning Spray Wash and Bactericidal Spray.	CCP(2) ...	Washing: 1. 90–100°F. 2. 345–2070 kPa (50–300 psi). Bactericidal Spray: 1. Organic acid: 1–2%. 115–130°F. 2. Chlorine: 50 ppm. Ambient temperature. 3. 70–275 kPa (10–40 psi) 4. Other applications per USDA–FSIS guidelines.	Continuous monitoring of temperature, pressure and bactericidal rinse concentration..	Washing: adjust temperature or pressure. Bactericidal spray: adjust temperature, pressure or concentration Examine and repair equipment as needed.	Post-skinning wash spray and bactericidal spray log. Log of preventative maintenance.	Supervisory review of records. Periodic microbiological analyses for aerobic mesophiles and/or Enterobacteriaceae coupled with trend analysis to confirm adequacy of process in comparison to data collected at CCP(1). Periodic testing of equipment to ensure it is operating according to design specifications.
Evisceration	CCP(3) ...	0% occurrence of the following defects for a single carcass: Fecal material, ingesta, urine or abscesses.	Employee observes contamination and routes contaminated carcass for immediate trimming.	1. Trained employee immediately trims defect area on carcass. 2. Add operators. 3. Reduce chain speed. 4.4. Sanitize soiled evisceration tools with 180°F water. 5. Sanitize soiled clothing 120°F water or appropriate sanitizer.	Random post-evisceration carcass examination log.	Supervisory review of records and operations. Random examination of carcasses after evisceration using a sampling plan sufficient to assure process control.

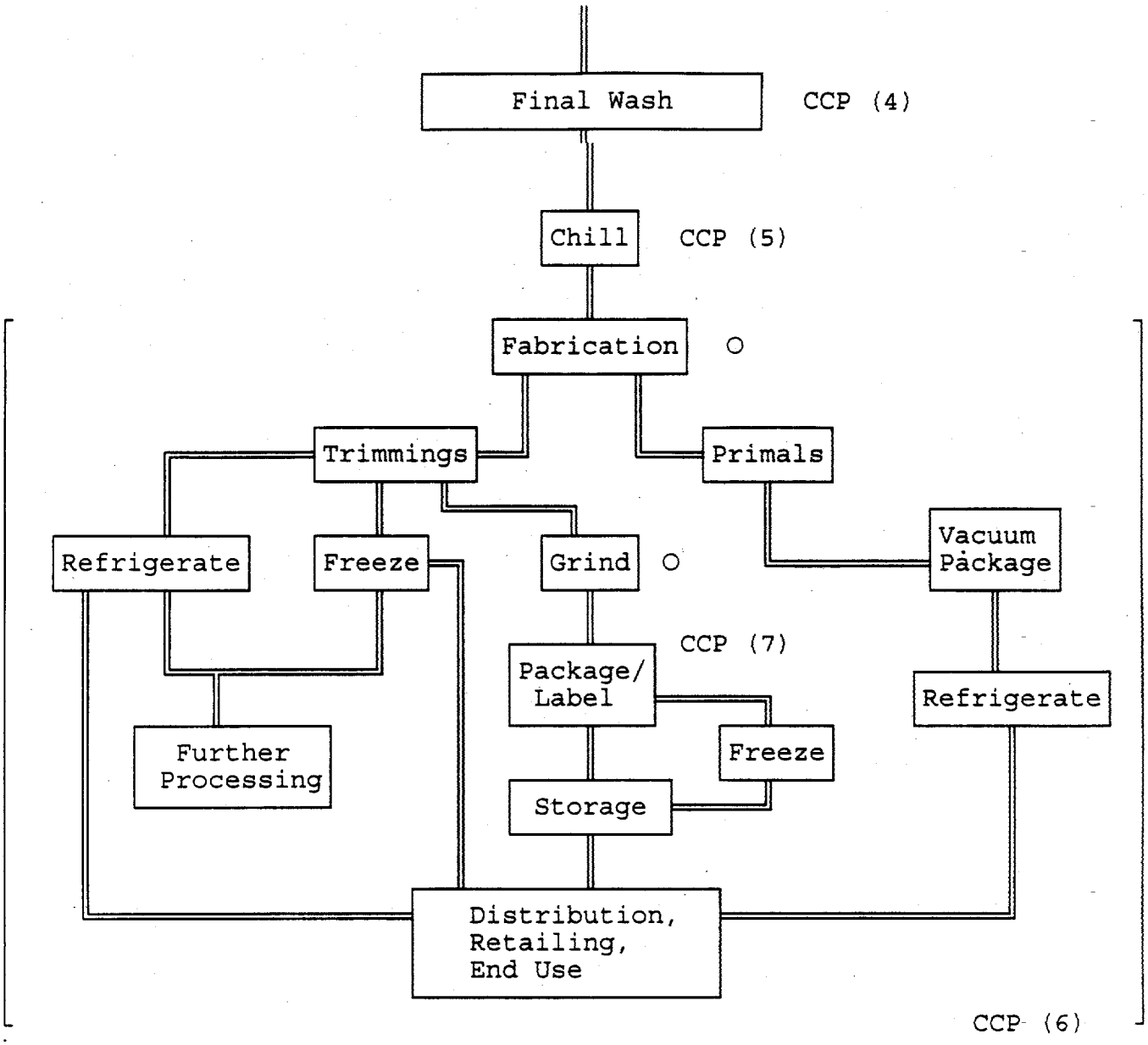
TABLE 1.—GENERIC HACCP PLAN CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION—Continued

Process/step	CCP	Critical limits	Monitoring procedure/frequency	Corrective action	Records	Verification
Final Wash Spray and Bactericidal Spray.	CCP(4) ...	Washing: 1. 90–100°F. 2. 345–2070 kPa (50–300 psi). Bactericidal Spray: 1. Organic acid: 1–2%. 115–130°F. 2. Chlorine: 50 ppm. Ambient temperature. 3. 70–275 kPa (10–40 psi). 4. Other applications per USDA–FSIS guidelines.	Continuous monitoring of temperature, pressure and bactericidal rinse concentration.	Washing: adjust temperature or pressure. Bactericidal spray: adjust temperature, pressure or concentration. Examine and repair equipment as needed.	Final wash spray and bactericidal spray log. Log of preventative maintenance.	Supervisory review of records. Periodic microbiological assays for aerobic mesophiles and/or Enterobacteriaceae to confirm an adequate reduction in bacterial numbers compared to baseline data collected at CCP(1) and CCP(3). An effective organic acid decontamination system is indicated by a ≤90% reduction in bacterial numbers from CCP(1) to CCP(4). Periodic testing of equipment to ensure operation in accordance to design specifications.
Chill	CCP(5) ...	Deep muscle (6 in.) temperature of ≤45°F within 36 hours, reaching ≤50°F after the first 24 hours. Carcasses spaced a minimum of 1–2 inches apart.	Continual confirmation of environmental conditions (e.g., room temperature, air velocity, humidity, etc.) that influence cooling rates. Monitor carcass spacing upon arrival to chill coolers. Conduct random temperature monitoring of carcasses after appropriate chill time.	Adjust carcass spacing. Adjust chill cooler temperature, air velocities, etc. Alert maintenance if cooler unit is not functioning properly. Continue chilling carcass until internal temperature reaches ≤45°F.	Chill log	Supervisory review of records. Review thermometer calibration log and spacing control charts. Periodic monitoring of cooling rates of deep muscle tissue through the use of temperature recording devices.
Refrigerated Storage.	CCP(6) ...	Product temperature of ≤45°F).	Check product temperature. Continuous monitoring of temperatures of storage facility.	Adjust temperature of storage facility. Place product on hold (i.e., retain), investigate, and take appropriate action.	Temperature records.	Supervisor record review.
Labeling	CCP(7) ...	Instructional labels and logo. Product date	Visual checks of each lot. Inspection of product to ensure use of correct instructional label and/or logo.	Assure correct label and relabel if incorrect.	Labeling records	Supervisory review of records.

FIGURE 1. BEEF SLAUGHTER, FABRICATION, AND PACKAGING

○ Potential site of minor contamination
● Potential site of major contamination




Final Wash
CCP (4)
Chill
CCP (5)
Fabrication
O
Trimmings
Primals
Refrigerate
Freeze
Grind
O
Vacuum Package
CCP (7)
Package/ Label
Refrigerate
Further Processing
Freeze
Storage
Distribution, Retailing, End Use
CCP (6)

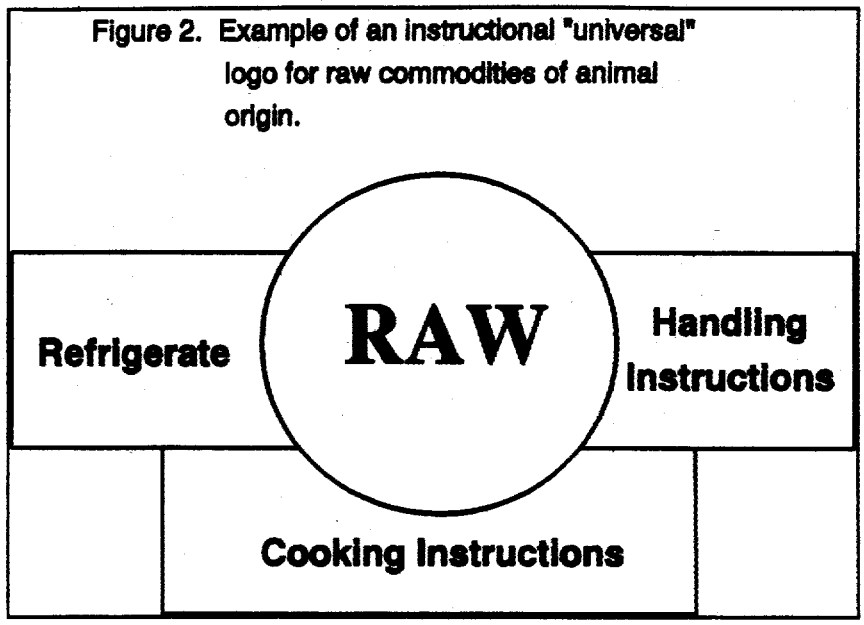


Figure 2. Example of an instructional "universal" logo for raw commodities of animal origin.

BILLING CODE 3410–DM–C

VI. Role of Regulators and Industry in HACCP-based Beef Processing

The processor has primary responsibility for development and implementation of HACCP plans for beef slaughter, fabrication, packaging and distribution. These plans, however, must consider the entire food system from production to consumption. The major role of the regulatory agency(s) is to verify that the processor's HACCP system is effective and working as intended. In general, this includes assurance that following the HACCP plan fulfills the intended purpose of providing a product that is safe when properly handled and prepared for consumption.

The role of regulatory agency(s) in inspection of beef processing operations should be based on the recommendations of the HACCP Subcommittee on ''The Role of Regulatory Agencies and Industry in HACCP''. The regulatory agency(s) in cooperation with industry and other experts in HACCP shall be actively involved in promoting the HACCP principles and their application to assure uniformity and common understanding. Regulations and guidelines that are promulgated by the regulatory agency(s) should be consistent with these principles.

The focus of the regulatory agency(s) should be on those activities associated with verification of critical control points. The processor must make HACCP records available to the regulatory agency(s). These records would include the processor's HACCP plan, CCPs, critical limits, monitoring, deviations, product disposition, and corrective actions. The HACCP plan and associated processor records must be considered proprietary information that must not be made available outside the regulatory agency(s).

Specific verification procedures may include: Establishing verification inspection schedules based on risk; review of the HACCP plan; review of CCP records; review of deviations and corrective actions; visual inspection of operations, random sampling of final products; review of critical limits; review of the processors verification records; review of revalidation of the HACCP plan; and review of HACCP plan modifications. The regulatory agency(s) should establish the manner and frequency of verification, format for verification reports, and other activities based on the HACCP Subcommittee recommendations (NACMCF, 1992).

Industry's responsibility is to develop, implement and maintain an effective HACCP system. The system should be based on the NACMCF recommendations on HACCP principles and application (NACMCF, 1992). Each facility should develop an HACCP team and provide for proper training in HACCP principles. It is the processor's responsibility to provide HACCP records to the regulatory agency(s). The processor must assure that the records are complete, accurate and up to date. Records for review must include pertinent information for verification and revalidation of the HACCP plan. When necessary, amendments to the HACCP plan will be made in response to the regulatory inspection.

It is recommended that the beef processors and associated regulatory agency(s) adopt the principles for implementation of HACCP as outlined by the HACCP Subcommittee on the Role of Regulatory Agencies in HACCP. These recommendations include uniformity in adopting HACCP principles, the characteristics of a HACCP-based inspection program, and procedures to facilitate the adoption and implementation of HACCP.

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VII. New Technologies and Procedures

New technologies and procedures for improved microbial control during the slaughtering process fall into two activities: preventing contamination and decontamination. Both will be considered. In addition to microbial control, improvements in carcass identification and product coding can be beneficial for determining the source of microbial pathogens.

A. Reducing the Potential for Contamination

This section includes those new technologies or improvements in existing procedures which can be used during slaughtering to reduce contamination from current levels to lower levels. Operators of slaughter facilities should be encouraged to

develop procedures which reduce or control the spread of pathogens from manure, internal organs, hair, water, etc. to the carcass or the processing environment. Such systems might include improved methods for hide removal; dehairing before removing the hide; washing and/or sanitizing saws, knives or other equipment during slaughtering operations; or other new techniques.

The trim rail, for example, should be moved to an area as far forward in the slaughter process as possible, preferably before the pre-evisceration wash. Such a move would facilitate preventing carcass contamination. This trim area should also be used to trim bruises, lesions, and grubs before spraying the carcass with water or other approved solutions.

The method of cutting around and handling the bung (e.g. tying off, covering, etc.) is another example. The preferred method has been debated for a number of years. There is general agreement, although there is little or no published data, that this step can be a significant source of contamination to the carcass. It is recommended that this step be reviewed and one or more methods be specified which will minimize carcass contamination.

B. Decontamination

There are two basic approaches to decontamination. The first approach usually consists of spraying carcasses during slaughtering and/or chilling. These procedures can reduce but will not destroy all the enteric pathogens. The second approach consists of irradiating packaged meat. Irradiation doses currently approved for use with poultry (Cross, 1992) would be sufficient to destroy the levels of enteric pathogens that would normally be present on freshly packaged meat.

Both approaches require that the slaughtering process be controlled to minimize contamination. The number of enteric pathogens on the carcasses should be as low as possible before either method of decontamination is applied. In addition, the method of decontamination and the organoleptic quality of the decontaminated meat must still be acceptable to consumers.

1. Organic Acid Sprays, etc.

Research and commercial experience has demonstrated that microbial contaminants on the surface of carcasses can be reduced through the use of organic acid sprays, hot water, steam and various combinations of these and other approved bactericidal materials. There may be more than one combination of treatments at one or more steps during slaughtering and/or chilling. The Committee encourages the development and implementation of such bactericidal systems to reduce the number and incidence of enteric pathogens on carcasses and fresh meat. As systems are developed and approved, FSIS should consider requiring the use of systems that have been proven to actively reduce enteric pathogens. The minimum efficacy required for such systems should be a specified reduction of Enterobacteriaceae (e.g. a 10-fold reduction) using standardized protocols recognized by the regulatory agency with input from other interested parties (e.g., academia, industry, USDA–ARS, NACMCF, and professional organizations). The conditions (e.g., time, temperature, pH, acid concentration, etc.) for effective operation of the decontamination system should be specified in the HACCP plan of the slaughter establishment.

In addition to its use as an in-line system for decontamination, this technology can be applied to unique situations. For example, under current inspection procedures for cattle, the following occurs in the event that during evisceration a break in viscera contaminates the body cavity:

Carcass siderailed;

Carcass trimmed by peeling out fascia in body cavity;

Exposed bone is trimmed; and

Visual reinspection.

An alternate approach to the above may be the following:

Carcass siderailed.

Decontamination of the body cavity by:

Extensive body cavity and carcass wash with potable water.

Decontamination of the body cavity by an approved procedure (e.g., organic acid, alkaline solution, hot water, steam, etc.)

2. Irradiation

Irradiation is an effective technology for destroying enteric pathogens in fresh meats. The irradiation of poultry for pathogen control has been approved in the United States and ten other countries (e.g., France, United Kingdom, and The Netherlands) (ICGFI, 1992). Irradiation of raw beef should, likewise, be approved. Used appropriately, irradiation can be an effective method for assuring the safety of raw meats, particularly raw ground beef.

C. Carcass Identification, Product Coding

Procedures should be developed so that carcasses can be identified as to source and can be traced back to the farm. In addition, minimum requirements for the coding of raw beef products should be developed so that information can be obtained relative to processing establishment(s), sources of raw materials and time of production.

References

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2. ICGFI. 1992. Ninth Meeting of the International Consultative Group on Food Irradiation. Inventory of product clearances. International Consultative Group on Food Irradiation, Joint FAO/IAEA Division, International Atomic Energy Agency, Vienna.

VIII. Research Needs

1. Recent research has indicated that the attachment of enteric pathogens involves a specific, genetically-controlled interaction between the bacterial cell surface and connective tissue. Further research is needed to confirm these observations and elucidate the underlying biochemistry of attachment. Potentially, this information could be used to develop enhanced methods for preventing contamination and/or enhancing the removal of enteric pathogens from raw beef.

2. One of the long standing questions with raw meat and poultry products has been the epidemiological significance of low numbers of infectious bacteria such as *Salmonella*, *Listeria*, and *E. coli* O157:H7. Recent biotechnological advances allow for the first time the active tracing of such foodborne pathogens from the farm, through the processing operations, and to ultimate isolation in a clinical setting. An active surveillance study should be undertaken to establish unequivocally the role of raw meat and poultry in transmission of human enteric diseases.

This research should be designed and conducted to identify the major points of introduction and/or dissemination of *Salmonella* and *E. coli* O157:H7. This information is needed to perform accurate hazard analyses and risk assessments to develop preventive measures on the basis of sound information.

The study should be conducted in a manner that permits acquisition of quantitative information of the levels of pathogens related to overt disease. While the establishment of an absolute Minimum Infectious Dose for individuals is not a reasonable

objective, there is a need to know on a population basis the incidence of active infections that are likely to occur as a function of levels enteric pathogens ingested. This information is needed to make realistic, cost-effective decisions concerning microbiological criteria. For example, if the infection rate at 10,000 cfu/g is 90% whereas at 100 cfu/g it is 0.01%, one could estimate risk factors versus the cost of achieving a significant improvement in public health. Using the cited example, it is unlikely that there would be much practical significance in mandating a minimum level of less than 1 cfu/g if there was not further reduction in infection rate.

3. Determine how techniques in microbial risk assessment can be applied to the transmission of bacterial pathogens via raw beef products. This includes quantifying the relative importance of both the different potential sources of pathogenic bacteria and the critical control points that control the microbiological hazards associated with beef slaughter operations.

4. Establish baseline data for the types and extent (level) of microbial contamination that can be expected on raw beef products produced under good manufacturing conditions. These data will serve as the basis for assessing the efficacy of alternate intervention approaches. This should include an examination of large and small volume slaughter operations for fed-cattle and dairy cattle to determine factors that effect incidence of foodborne pathogens in these segments of the beef industry.

These surveys should be accompanied with an evaluation of the relationship between the results of traditional organoleptic inspections and assessments of both the incidence and extent of contamination with specific human pathogens. Particular emphasis should be directed to assessing the relationship between animal health at the time of slaughter and the overall degree of contamination of the meat.

5. Surveys of the adequacy of refrigeration in distribution channels, retail markets, food service establishments, and the home have indicated that there is a significant potential that raw beef products will be temperature abused before consumption. There is a need to establish quantitative data on the impact of transitory or marginal temperature abuse on the growth of pathogens on raw beef products. Data on time/temperature relationships would provide a scientific basis for courses of action that should be followed when there is a loss of temperature control.

6. Establish how refrigerated raw beef should be stored to maximize microbiological safety, with particular reference to control of psychrotrophic pathogens.

7. Identify microbiological inhibitors that could be used in raw meat and poultry, particularly ground beef.

8. Evaluate decontamination procedures to determine if they could be employed as an alternate means to trimming for effectively eliminating fecal contamination from carcasses.

9. The continued development of improved methods for the identification of foodborne pathogens in meat and poultry products should be encouraged. This includes rapid methods that can be used both to identify animals that harbor enteric pathogens prior to slaughter and to periodically verify the effectiveness of HACCP operations. Studies of improved means for sampling to decrease lower limits of detection, enhance accuracy, and decrease number of samples required for statistical validity should also be encouraged.

10. It is often assumed that enteric pathogens are limited to the surface of beef carcasses. However, evidence indicates that lymph nodes can harbor enteric pathogens (e.g., salmonellae). This suggests that the processing procedures described in this document would be less effective than anticipated. The relative significance of beef carcass lymph nodes as a potential source of *Salmonella* and *E. coli* O157:H7 is unknown. Studies should be undertaken to determine the incidence of these pathogens in bovine lymph nodes.

Attachment A—General Sanitation Controls for Beef Slaughter and Fabrication Operations

Successful implementation of HACCP within a beef slaughter or fabrication facility requires the following basic plant support programs. Good manufacturing practices (GMPs) must be stressed throughout the facility. These practices include programs that cover employee personal hygiene, effective sanitation, pest management, equipment selection and maintenance, plant environmental management, potable water sources, operational practices, and proper storage of packaging materials and supplies. Effective adherence to GMPs requires orientation and follow-up training for all employees.

A. Hygiene Practices

All personnel should be trained in the importance of personal hygiene.

Hair nets, beard covers, knives, steels, lockers, aprons, smocks, boots, etc., should be handled and maintained in a clean and sanitary manner. Disposable personal items should be changed as required to assure cleanliness.

Hot water sanitizing stations should be kept at 180°F with frequent changes of water. After knives are dipped they should be sanitized by approved sanitizers for an appropriate time interval before reuse. This may require multiple knives to allow adequate time in the sanitizer to assure proper microbial kill.

Knives and all personal equipment should be cleaned, sanitized, and dried prior to storage. Special attention should be given to boots and footwear. Storage lockers should be kept clean and free of dirty clothes, rags, etc.

Shrouds, aprons, gloves, and cotton items should be placed in a marked plastic container after use. These items should be given a proper wash with a chlorine rinse and dried thoroughly before being returned to the processing plant.

B. Equipment

Acquisition of USDA approved equipment should include consideration of ease of cleaning, sanitation, and maintenance.

All equipment should be cleaned and sanitized daily. Pre-operative inspections should be conducted prior to start-up.

All equipment must be maintained in good repair. As materials age, deterioration occurs and care must be taken to monitor the equipment. Preventive maintenance helps ensure equipment works properly and facilitates proper cleaning and sanitizing.

Plastic or metal pallets are preferable, however, if unavailable, wooden pallets may be used provided they are kept dry and clean.

All plastic belts and other food conveyance surface should be inspected frequently, and replaced or resurfaced as soon as there is evidence of cracking, pitting, or other defects that would hamper effective cleaning and sanitizing.

A major equipment concern is controlling material buildup, i.e., bone dust and meat particle accumulation in areas that increase in temperature during processing. Such problems can be minimized by regular cleaning and appropriate documentation of all actions.

C. Movement of Personnel and Equipment

Movement of personnel and equipment between areas, particularly between slaughter and fabrication or

processing zones can be a source of cross contamination.

Fork lifts can be a continuing source of cross-contamination. Movement must be excluded from areas where product is exposed.

Movement of personnel between zones should be controlled and minimized. Sinks, boot washes, and clean outer garment exchange should be used at zone entrances, particularly if individuals are moving from a ''dirty'' zone to a ''clean'' area (e.g., movement from abattoir to fabrication room).

D. Packaging

A basis for selection of approved food packaging material should be effectiveness for protecting the product and preventing contamination. Packaging integrity must be maintained to avoid recontamination, i.e., proper seals, clips, covers, vacuum levels, etc. All packaging materials and supplies should be received and stored in manner that ensures their integrity.

E. Pest Control

An active program for control of insects, rodents, wild birds, and other pests should be maintained, including periodic examination of facilities for evidence of infestations.

F. Plant Environment Management

The processing environment should be maintained to meet GMP requirements. This includes daily operative checks to ensure compliance.

G. Water

Water for processing should be obtained from a potable source or where permitted, recycled according to approved guidelines. Periodic analysis of the water should be conducted to ensure that the source meets the recognized microbiological criteria for potable water.

General Guidelines for the Handling of Raw Beef Products in Retail Food Stores and Food Service Establishments

A. Food Receiving and Storage

Raw beef products should be received in good condition and at a temperature of 40°F or less. A visual inspection should be conducted to assure the condition of raw beef products.

B. Refrigerated Storage

Storage temperatures of less than 40°F will minimize microbial growth of *Salmonella.* Proper stock rotation should be practiced and:

A first-in, first-out stock rotation system should be utilized. All foods should be kept covered, wrapped, dated, labelled and rotated. Older products should be used before newly received foods.

Raw products should be stored separately from cooked, ready-to-eat products to prevent cross-contamination.

The cooler should be regularly inspected for good sanitary conditions and maintained at the proper temperature (<40°F) and humidity. Products should be stored to assure sufficient air circulation.

C. Food Preparation

Delicatessen employees and food service workers should be aware of and practice good personal hygiene at all times, especially when preparing and handling foods.

Employees should not work when ill and should wash hands frequently, especially after handling raw foods and after using the restroom.

Clean clothing and appropriate hair cover should be worn by all personnel involved in food preparation.

Raw foods should be kept separate from cooked, ready-to-eat foods. Equipment and utensils used in the preparation of raw beef products should be properly cleaned and thoroughly sanitized before use with other foods.

Intact cuts of beef (roasts, chops, etc.) should be cooked to a minimum internal temperature of 140°F. The temperature should be checked with a good quality thermometer in the thickest part of the meat.

Hamburgers and other ground or restructured beef products should be cooked to a minimum internal temperature of 155°F. At this temperature, the meat is well done and has no pink color.

Beef products that are cooked and held for hot display should be kept at a temperature of at least 140°F.

Leftover meat products should be refrigerated immediately in shallow containers so quick cooling can be achieved and microbial growth can be prevented.

Reheat leftover meats and other precooked beef products to a minimum internal temperature of 165°F.

General Guidelines for the Handling of Raw Beef Products by Consumers

A. Food Purchasing

Buy perishable foods last, after all other grocery items have been selected. Insist that grocery baggers place all raw food of animal origin (red meat, poultry, seafood, eggs, etc.) in a separate plastic bag for transport. Never allow raw meat to contact a package of food that will not be cooked before consumption. Cold foods should be placed together in a paper bag to help prevent excessive warming during transport.

Take purchases home immediately and place items to be kept refrigerated or frozen in proper storage as soon as possible.

B. Kitchen Appliances and Utensils

Use a thermometer to assure refrigerator temperature is 40°F or below and that freezer temperature is below 0°F.

Keep refrigerator and freezer shelves clean and sanitize periodically.

Separate raw from cooked foods in the refrigerator or freezer. Raw foods should never be stacked on top of cooked foods.

Use an oven thermometer to verify that the oven temperature is approximately the same as the temperature dial selector. Most oven owner's manuals will have instructions for adjusting the temperature selector for accuracy.

Counter tops, sinks, and cutting surfaces should be cleaned and sanitized after contacting any raw food. Clean surfaces with hot soapy water and rinse thoroughly. Sanitize the surface with a chlorine solution (one cap of bleach in one gallon of cold water; a new solution prepared weekly).

If washing utensils by hand, knives and cutting boards used with raw meats should be washed with hot, soapy water, followed by a hot water rinse and sanitation with a chlorine solution after each use. Washing in a dishwasher having a hot water rinse will sufficiently sanitize utensils (the temperature of the rinse should be at least 120°F).

C. Food Preparation

Cross-contamination occurs when utensils, plates, or hands used in preparing raw foods are not thoroughly washed and sanitized before using with cooked foods or foods that will not be cooked (e.g., salads). Never use the same plate to transport raw and cooked beef unless thoroughly washed and sanitized between uses.

Frozen products should be thawed in the refrigerator or under cold running water.

Cook intact beef cuts (roasts, chops, etc.) to a minimum internal temperature of 140°F. Always check temperatures with a meat thermometer at the thickest part of the meat.

Hamburgers and other ground or restructured beef products should be cooked until the meat is well-done (no pink color, juices run clear). The temperature at the coolest portion of the meat should reach 155°F.

Cold beef should be stored and served at 40°F or less.

Leftovers should be refrigerated immediately in shallow containers to

prevent bacterial growth. Allowing a cooked food to ''cool down'' at room temperature before refrigerating may allow bacterial growth.

Reheat leftovers and other precooked beef products to an internal temperature of 165°F.

ATTACHMENT D: CONTROL POINTS AND CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION

○ Potential site of minor contamination.
• Potential site of major contamination.

Process/step	○, •, CCP	Criteria or critical limits	Monitoring procedure/frequency	Corrective/preventive action	Records	Verification
Cattle receiving:						
Pens	○	Pens dry and clean.	Visual check each shift.	Reclean. Remove standing water.	Receiving/holding log.	Supervisory review of records.
Cattle holding.	○	Holding <24 h ...	Check holding records each shift.	Coordinate holding and slaughter speed.	Receiving/holding log.	Supervisory review of records.
Stunning:						
Bleeding	.....	Sanitize knife (180 °F water) between sticks.	Visual checks and water temperature checks each shift.	Correct procedures and temperature.	None	Supervisory review.
Head/shank removal:						
Skinning	CCP(1) •	≤20% of carcasses with dressing defects.	Operator observes effectiveness of skinning process for each carcass. Visual analysis should be conducted under adequate lighting per USDA requirements..	Add operators. Reduce chain speed. Conduct carcass trimming.	Random post-skinning carcass examination log.	Examination of random carcasses after skinning is complete using sampling plan sufficient to assure process control. Supervisory review of records. Initially, conduct microbiological analyses for aerobic mesophiles and/or *Enterobacteriaceae* to establish baseline data on expected bacterial numbers. Periodic follow-up analyses and trend analysis to verify process control. Review control charts to confirm that sampling frequency is sufficient to detect 20% defect criteria.
Post-skinning spray wash and bactericidal spray.	CCP(2) ...	Washing: 1. 90–100 °F. 2. 345–2070 kPa (50–300 psi). Bactericidal Spray: 1. Organic acid: . 1–2% 115–130°F. 2. Chlorine: x 50 ppm. ..... Ambient temperature ..... 3. 70–275 kPa (10–40 psi) .... 4. Other applications per USDA–FSIS guidelines.	Continuous monitoring of temperature, pressure and bactericidal rinse concentration.	Washing: adjust temperature or pressure. Bactericidal spray: adjust temperature, pressure or concentration. Examine and repair equipment as needed	Post-skinning wash spray and bactericidal spray log. Log of preventative maintenance.	Supervisory review of records. Periodic microbiological analyses for aerobic mesophiles and/or *Enterobacteriaceae* coupled with trend analysis to confirm adequacy of process in comparison to data collected at CCP(1). Periodic testing of equipment to ensure it is operating according to design specifications.

ATTACHMENT D: CONTROL POINTS AND CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION—Continued

○ Potential site of minor contamination.
• Potential site of major contamination.

Process/step	○, •, CCP	Criteria or critical limits	Monitoring procedure/frequency	Corrective/preventive action	Records	Verification
Evisceration	CCP(3) •	0% occurrence of the following defects for a single carcass: Fecal material, ingesta, urine or abscesses.	Employee observes contamination and routes contaminated carcass for immediate trimming.	1. Trained employee immediately trims defect area on carcass. 2. Add operators 3. Reduce chain speed. 4. Sanitize soiled evisceration tools with 180°F water. 5. Sanitize soiled clothing with 120°F water or appropriate sanitizer	Random post-evisceration carcass examination log.	Supervisory review of records and operations. Random examination of carcasses after evisceration using a sampling plan sufficient to assure process control.
Viscera handling.	•	No viscera contamination of carcasses.	Visual checks	Correct defects ..	None	Supervisory review of operations.
Splitting	○	Clean saw and sanitize in 180 °F water.	Visual checks	Reclean saw	None	Supervisory review of operations.
Final wash spray and bactericidal spray.	CCP(4) ...	Washing: 1. 90–100 °F. 2. 345–2070 kPa (50–300 psi). Bactericidal Spray: 1. Organic acid: . 1–2%. 115–130°F. 2. Chlorine: 50 ppm. Ambient temperature 3. 70–275 kPa (10–40 psi). 4. Other applications per USDA–FSIS guidelines.	Continuous monitoring of temperature, pressure and bactericidal rinse concentration.	Washing: adjust temperature or pressure. Bactericidal spray: adjust temperature, pressure or concentration. Examine and repair equipment as needed.	Final wash spray and bactericidal spray log. Log of preventative maintenance.	Supervisory review of records. Periodic microbiological assays for aerobic mesophiles and/or *Enterobacteriaceae* to confirm an adequate reduction in bacterial numbers compared to baseline data collected at CCP(1) and CCP(3). An effective organic acid decontamination system is indicated by a >90% reduction in bacterial numbers from CCP(1) to CCP(4). Periodic testing of equipment to ensure operation in accordance to design specifications.

ATTACHMENT D: CONTROL POINTS AND CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION—Continued

○ Potential site of minor contamination.
• Potential site of major contamination.

Process/step	○, •, CCP	Criteria or critical limits	Monitoring procedure/frequency	Corrective/preventive action	Records	Verification
Chill	CCP(5) ...	1. Deep muscle (6 in.) temperature of ≤45 °F within 36 hours, reaching ≤50 °F after the first 24 hours. 2. Carcasses spaced a minimum of 1–2 inches apart.	Continual confirmation of environmental conditions (e.g., room temperature, air velocity, humidity, etc.) that influence cooling rates. Monitor carcass spacing upon arrival to chill coolers. Conduct random temperature monitoring of carcasses after appropriate chill time sufficient to maintain process control.	Adjust carcass spacing. Adjust chill cooler temperature, air velocities, etc. Alert maintenance if cooler unit is not functioning properly. Continue chilling carcass until internal temperature reaches ≤45 °F. Product should not be moved to the next step in processing until temperature is reached.	Chill log	Supervisory review of records. Review thermometer calibration log and spacing control charts. Periodic monitoring of cooling rates of deep muscle tissue through the use of temperature recording devices.
Fabrication (cut up).	○	1. Product temperature of ≤45°F. 2. Product transported through fabrication procedures and into storage within 1 hour..	Checks of product temperature. Continuous monitoring of room temperatures. Check speed of product movement through fabrication.	Adjust room temperature. Adjust speed of incoming product to accommodate 1 hour fabrication room limit.	Temperature and product speed records.	Supervisory review of records.

Note: The following Supplement will not appear in the Code of Federal Regulations.

Supplement—Preliminary Regulatory Impact Assessment for Docket No. 93–016P, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems''

Table of Contents

I. HACCP Produces Net Benefit to Society

Food Safety and Inspection Service (FSIS) is proposing, in docket no. 93–016P, above, to require all federally inspected meat and poultry plants to adopt a Hazard Analysis and Critical Control Points (HACCP) processing control system for each of its processes within 3 years of publication of the final rule. The proposed regulations also mandate some near-term pathogen reduction interventions prior to HACCP plan implementation. In the same document, FSIS provides advance notice of plans to establish interim targets, guidelines, and standards to establish public health goals for pathogens.

The objective of these regulations is to initially reduce and eventually minimize the risk of foodborne illness from four human pathogens in meat and poultry in the manufacturing sector under current production technologies. These pathogens are:

1. *Campylobacter jejuni/coli;*
2. *Escherichia coli 0157:H7;*
3. *Listeria monocytogenes; and*
4. *Salmonella.*

These regulations also require appropriate controls to minimize or prevent other biological, chemical and physical safety hazards. To a certain extent HACCP can improve quality aspects of products and production efficiency. However, the benefits assessed here are based only upon pathogen reduction and control for safety.

FSIS has selected mandatory HACCP as the centerpiece for this new regulatory program because scientists and industry leaders agree that it provides the most effective food processing controls available to reduce and control meat and poultry pathogens and accomplish other food safety objectives such as chemical residue control.

The function of this regulatory impact assessment is to evaluate the costs and benefits of a mandatory HACCP-based regulatory program for all meat and poultry establishments under inspection. The HACCP ''program'' includes all the interventions in this proposal. Because contamination can occur any place in the production process, no one intervention can minimize the risk; indeed, the value of the HACCP system is that it provides a framework for systematically using interventions to minimize risk. For this reason benefits have been estimated only for the entire HACCP program. Costs are provided for each individual intervention. (A Supplement on Costs is available from Diane Moore, Docket Clerk, Room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.)

Because there are no scientific data that can be used to relate intermediate pathogen reductions to reductions in foodborne illness, benefits have been based on the Agency's intention to minimize the risk of foodborne illness in the manufacturing sector. Risk minimization means the elimination of almost all the foodborne illness caused by the contamination of meat and poultry products with the four pathogens listed above in inspected plants. The amount of reduction in pathogens needed to do this is unknown and would vary for individual pathogens and products. The testing requirement will enable the Agency to learn more about what pathogen reduction standards would be appropriate to minimize risk.

The conclusion of the cost-benefit analysis is that mandating HACCP-based processing control systems will result in net benefits that far exceed implementation and operation costs. Table 1 provides a summary of these costs and benefits. The proposed regulation will redistribute costs in a fashion more acceptable to societal values which have always given priority to minimizing the occurrence of controllable diseases.

TABLE 1.—COST-BENEFIT COMPARISON HACCP/PATHOGEN REDUCTION PROPOSAL

(Millions of $—discounted 20 years)*

	Costs		Benefits**
Total	$2,298.9	Total	$6,422–23,935
Near-Term:		Foodborne illness avoided:.	
Micro testing	131.9	Campylobacter jejuni/coli	2,919–4,670
Sanitation SOP	86.6	E. coli 0157:H7	1,168–2,419
Time/Temperature Requirements	45.5	Listeria monocytogenes	584–1,168
Antimicrobial Treatments	51.7	Salmonella	1,751–15,178
Subtotal	315.7		
HACCP Implementation:			
Plan development	35.7		
Micro testing	1,262.5		
Record keeping	456.4		
HACCP Training	24.2		
Aseptic Training	1.9		
Fed. TQC Overtime	20.9		
Agency Training	0.4		
SOP under HACCP	181.2		
Subtotal	1,983.2		

Source: Economic Research Service, Centers for Disease Control and Prevention, and Food Safety and Inspection Service.

*These costs have been discounted using the OMB suggested rate of 7%.

**Benefits from elimination of *Salmonella, E. coli 0157:H7, Campylobacter jejuni/coli* and *Listeria monocytogenes* are estimated at 90% of the total meat- and poultry-related medical costs and productivity losses associated with each pathogen as depicted in Table 4. Total benefits start 5 years after publication of final rule.

It is not known exactly what percentage of contamination takes place in the manufacturing sector in contrast to that which occurs afterwards during distribution and preparation. It is clear that most contamination takes place during manufacturing since it derives from processing animals and cross contamination during further processing. Agency microbiologists have estimated that about 90 percent of pathogen contamination occurs within

the manufacturing sector, and accordingly, only 90 percent of the benefits from the reduction of foodborne illness costs have been included as benefits in the analysis.

FSIS expects it to take about five years from the publication of the final rule for the proposed interventions and HACCP to reach the risk minimization goal. By that time, all establishments will have implemented effective pathogen reduction interventions and will have been systematically controlling their processes for from 2 to 4 years. Although there is reason to believe that during the first five years, significant benefits will be generated by the interventions and controls in place, there are no data to estimate these benefits.

Sensitivity Analysis for Table 1

The calculation of benefits in table 1 assumes benefits are zero for years 1 to 4 and the maximum possible (i.e., 100 percent of the 90 percent attributable to contamination in the inspected plants) for years 5 to 20. Given achievement of the estimated benefits in years 5 through 20, actual benefits to society would likely exceed these benefit estimates for several reasons. These reasons include the conservative valuation of a human life, no consideration of consumers' willingness to pay for avoidance of illness, and the assumption of zero benefits from near-term interventions and early implementation of HACCP. The achievement of maximum benefits is also subject to uncertainty.

In order to account for the possibility of positive benefits in years 1 through 4 and the uncertainty of benefits in years 5 through 20, an analysis was performed to examine the sensitivity of the cost-benefit analysis to changes in the estimated stream of benefits. The results of this analysis are presented in table 1A, and a discussion of the assumptions used in this analysis follows.

First, the assumption of zero benefits until year 5 is replaced by the assumption that benefits grow linearly starting from zero and reach the undiscounted maximum of $0.99–$3.7 billion in year 5. Thus, the low and high end estimates of undiscounted benefits in the first year are $0.198–$0.74 billion. Benefits increase in year 2 to $0.396–$1.48 billion and increase at the same rate until year 5. The discounted value of benefits for years 1 to 4 is $1.733 to $6.478 billion. The discounted value of benefits over 20 years becomes $8.155–$30.413 billion.

SENSITIVITY ANALYSIS OF ALTERNATIVE BENEFIT LEVELS

	Added benefits, years 1–4[1]		Baseline benefits[2]		Reduced benefits, years 5–20[3]	
	Low	High	Low	High	Low	High
Year	Billion dollars, discounted at 7 percent					
1	0.20	0.74	0	0	0	0
2	0.37	1.38	0	0	0	0
3	0.52	1.94	0	0	0	0
4	0.65	2.41	0	0	0	0
5	0.76	2.82	0	0	0	0
Sum of benefits, years 1–4	1.73	6.48	0	0	0	0
Sum of benefits, years 5–20	6.42	23.94	6.42	23.94	5.78	21.54
Total benefits, years 1–20	8.16	30.41	6.42	23.94	5.78	21.54
Benefit-cost ratio[4]	3.5	13.2	2.8	10.4	2.5	9.4

[1] Assumes benefits start at 0 and increase linearly to base level benefits in year 5.
[2] Base level of benefits are those presented in table 1.
[3] Assumes 90 percent of base level of benefits.
[4] Assumes costs presented in table 1.

Alternative assumptions regarding the size of benefits are possible. The linear assumption is arbitrary; the purpose is to demonstrate that any benefits in years 1 to 4 will increase the 20-year total discounted value of benefits.

Second, the assumption of zero benefits until year 5 is retained but the realized benefit in year 5 and later is reduced by 10 percent, making the annual undiscounted benefits $0.89–$3.32 billion. The discounted value of benefits over 20 years becomes $5.780–$21.542 billion. The uncertainty involved in estimating the annual cost of foodborne illness is already accounted for in the range reported in table 4. The 10 percent reduction is an arbitrary assumption to demonstrate the sensitivity of the cost-benefit analysis.

In neither case are costs affected. All estimates of discounted benefits are far larger than the discounted costs for each set of assumptions. The benefit-cost ratio ranges from 2.5:1 to 13.2:1.

Costs

Costs to meat and poultry processors across the Nation will vary according to how much improvement in process control each plant needs. Plants that now have good processing controls will have relatively few implementation costs, while plants that have little or no process control will need to spend more for implementation. A detailed analysis of industry's costs to develop, implement, and operate HACCP systems appears in Section V.

Costs to the Government would be for training FSIS employees. Existing resources would be used. No additional funding is anticipated.

Program Goals

The quantifiable benefits to society from the proposed regulation range from $6.4 to $23.9 billion as 20 years of foodborne illness and attendant costs to society are avoided. (The wide range of benefits is attributable to uncertainties in the data used to estimate the incidence of foodborne illness.)

The predictability of foodborne illness reductions from a reduction of pathogens in meat and poultry is made difficult by the fact that little quantitative data on the relationship between these two variables exists because many of the risk assessments necessary to establish this relationship have not been undertaken. Therefore, it is not known how much pathogens need to be reduced to minimize the risk of foodborne disease from meat and poultry. One component of the proposal is the testing of product to generate data on pathogen incidence which will help to elucidate the relationship between pathogen contamination and foodborne

disease, and the Agency also intends to undertake additional risk assessments to generate dose/response curves for specific pathogens. The Agency will use the new information from this research to adjust targets, if necessary, to meet its goal of risk minimization.

The Agency believes that it is reasonable to set a goal of risk minimization assuming the implementation of the requirements in this proposal. Current technologies can and frequently do produce product of minimal risk. Contamination occurs from poor practices (errors) and lack of systematic preventive controls throughout the production process. For the first time, in this proposal the Agency is focusing on reducing pathogens. It is mandating interventions that a large part of the industry already uses to correct errors that cause pathogen contamination, and it is proposing the use of a system of controls that prevents pathogens which is the most effective way of reducing them. Empirical evidence of how effective these interventions and HACCP process controls are where they are currently used and the Agency's knowledge that many establishments do not currently use them leads the Agency to believe that the risk of pathogens in the manufacturing sector can be minimized by the implementation and enforcement of these requirements for all inspected establishments.

Further, the Agency is mandating product testing for pathogens which will enable it to set targets that can establish a standard of pathogen control throughout the industry that will minimize the risk of foodborne illness.

II. Market Failure Justifies Regulation of Pathogens to Protect Public Health

Consumers make choices about the food they purchase based upon factors such as price, appearance, convenience, texture, smell, and perceived quality. In an ideal world, people would be able to make these decisions with full information about product attributes and choose those foods which maximize their satisfaction. In the real world, however, information deficits about food safety complicate consumer buying decisions.

Since all raw meat and poultry products contain microorganisms that may include pathogens, raw food unavoidably entails some risk of pathogen exposure and foodborne illness to consumers. However, the presence and level of this risk cannot be determined by a consumer, since pathogens are not visible to the naked eye. Although they may detect unwholesomeness from obvious indications such as unpleasant odor or discoloration caused by spoilage microorganisms, consumers cannot assume products are safe in the absence of spoilage. They simply have no clear-cut way to determine whether the food they buy is safe to handle and eat.

When foodborne illness does occur, consumers often cannot correlate the symptoms they experience with a specific food because some pathogens do not cause illness until several days after exposure. Thus, food safety attributes are often not apparent to consumers either before purchase or immediately after consumption of the food. This information deficit also applies to wholesalers and retailers who generally use the same sensory tests—sight and smell—to determine whether a food is safe to sell or serve.

The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by preventable pathogenic microorganisms. Consumers often cannot trace a transitory illness to any particular food or even be certain it was caused by food. Thus, food retailers and restaurateurs are generally not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors have little incentive to incur extra costs for more than minimal pathogen and other hazard controls. The widespread lack of information about pathogen sources means that businesses at every level from farm to final sale can market unsafe products and not suffer legal consequences or a reduced demand for their product. An additional complication is that raw product is often fungible at early stages of the marketing chain. For example, beef from several slaughterhouses may be combined in a batch of hamburger delivered to a fast food chain. Painstaking investigation by public health officials in cases of widespread disease often fails to identify foodborne illness causes; in half the outbreaks the etiology is unknown.

Most markets in industrialized economies operate without close regulation of production processes in spite of consumers having limited technical or scientific knowledge about goods in commerce. Branded products and producer reputations often substitute for technical or scientific information and result in repeat purchases. Thus brand names and product reputations become valuable capital for producers.

In the U.S. food industry, nationally recognized brand names have historically provided significant motivation for manufacturers to ensure safe products. In recent years, more and more meat and poultry have come to be marketed under brand names.

Yet in the case of meat and poultry contaminated with pathogenic microorganisms, even brand name protection has not provided enough motivation for processors to produce the safest product they can make.

The failure of meat and poultry industry manufacturers to produce products with the lowest risk of pathogens and other hazards cannot be attributed to a lack of knowledge or appropriate technologies. The science and technology required to significantly reduce meat and poultry pathogens and other hazards is well established, readily available and commercially practical.

There are three main explanations for why a large portion of the meat and poultry industry has not taken full advantage of available science and technology to effectively control manufacturing processes.

1. Meat and poultry processing businesses are relatively easy to enter; there are no training or certification requirements for plant operators. Consequently, the level of scientific and technical knowledge of management in many plants is minimal.

2. The industry is very competitive and largely composed of small and medium-sized firms that have limited capital and small profits.

3. Management in many of these plants has little incentive to make capital improvements for product safety because they are not distinguishable by customers and therefore yield no income.

In spite of these barriers, many industry establishments do produce meat or poultry products using process controls that assure the lowest practical risk of pathogens and other hazards. But a significant part, particularly those producing raw products for consumers for further processing, do not.

FSIS has concluded that the lack of consumer information about meat and poultry product safety and the absence of adequate incentives for industry to provide more than minimal levels of processing safety represents a market failure requiring Federal regulatory intervention to protect public health.

Regulating Pathogens

The present combination of market regulation and industry self-policing has not resolved increasingly apparent problems with meat and poultry

pathogens. Documented cases of foodborne illness each year, some of which have resulted in death, represent a public health risk that FSIS judges to be unacceptable. A Federal regulatory program that reaches every level of meat and poultry production, processing, distribution and marketing is the only means available to society for lowering foodborne pathogen risks to an acceptable level. FSIS further concludes that a mandatory HACCP program is the only means of achieving this goal. Alternatives cannot achieve the reduction in pathogens necessary to assure the maximum reduction in food illness. To the extent that reductions in pathogen levels in meat and poultry can be achieved with current technology and without causing significant economic or social distortions, FSIS as a public health agency can support no alternative to HACCP.

The economic argument supporting HACCP is that its benefits to society outweigh the costs imposed by this proposal. Table 1 shows that in terms of the costs and benefits that can be quantified, HACCP implementation would generate considerable net benefits to society.

In addition, HACCP is supported by redistribution arguments that are based on widely accepted social values. Public health legislation itself clearly implies society's preference for having costs manifest themselves as regulatory or production costs rather than as costs associated with illness.

Even with demonstrated net benefits to society, it is important to keep the HACCP costs to industry down as much as possible to avoid unintended economic effects of HACCP implementation such as higher food prices or putting firms out of business. The use of systematic process control as reflected in the HACCP system would not require any establishment to change its production process, and the costs of monitoring a HACCP system are relatively small.

Thus, costs should have a minimal effect on the industry as a whole. Table 2 shows the increased cost per pound of product based on the estimated HACCP costs.

TABLE 2.—EFFECTS ON THE COST PER POUND OF MEAT AND POULTRY

Inspection program	1993 poundage* (billion)	Four-year estimated poundage (billion)	Near-term and HACCP implementation total costs (million)	Cost per pound
Total State and Federal	77.7	310.9	$733.5	$0.00236

*Poundage data is slaughter carcass weight for Federal and State establishments with 26 of 27 states reporting slaughter data.

A reduction in the incidence of foodborne illness is the principal performance goal for both USDA and industry. Mandatory HACCP implementation is projected to produce a direct reduction in foodborne illness with public health benefits estimated at $6.4–24.0 billion for 20 years (see Table 1). The Agency believes that these benefits clearly outweigh industry discounted costs of $2.3 billion associated with implementing and maintaining HACCP controls for 20 years.

III. Alternatives

A. Process Control Regulatory Strategy

FSIS has determined that effective process control is needed throughout the meat and poultry industry in order to minimize pathogen contamination and control other hazards in food products and lower the risk of subsequent foodborne illness. Accordingly, a regulatory strategy has been formulated to mandate process control improvements to achieve immediate reductions and an eventual minimization of the risk of meat and poultry pathogens in the Nation's food supply. Chemical and physical hazards will also be prevented. This strategy is supported by consumers, scientists, and the majority of meat and poultry industry processors who already recognize the benefits of good process control.

Process control is a proactive strategy that all segments of industry can undertake to anticipate manufacturing problems in advance and prevent unsafe foods from ever being produced. In practice, process control is a systematic means to:

- identify and control production hazards;
- determine control points in the processing system;
- establish standard measures for each control point;
- set procedures for plant workers to monitor requirements;
- provide clear instructions for appropriate corrective actions when a control point goes out of control;
- establish record-keeping to document control point measurements; and
- provide procedures for product verification tests to ensure system continues to operate as planned.

The process control strategy summarized in this paper is founded on three principles:

1. USDA regulatory policy should be focused on providing a solution to meat and poultry biological, chemical and physical hazards that present the highest public health risks;

2. Pathogenic microorganisms—which present the greatest foodborne risk to human health—are now present in significant percentages of raw meat and poultry products; and

3. These pathogens and resulting risks of foodborne illness can be largely avoided by uniform meat and poultry industry efforts to attain and maintain more effective methods of control during the manufacturing process.

The focus of this strategy is explicitly on prevention; it is designed to prevent the production of defective product as opposed to more costly and less effective detect-and-condemn methods.

Process control is not a substitute for inspection any more than inspection could be a substitute for process control. This distinction is important because Federal inspection was never intended to be—and cannot be—the front-line control for food safety in meat and poultry processing plants. Safety controls must be built into the manufacturing process and be administered continuously by industry. The objective of inspection in a process control environment is to assure that those controls are present, adequate and are being used properly.

The primary benefits of a process control regulatory strategy are that it will: (1) Provide industry the tools and incentive to reduce meat and poultry pathogens as a means to improve food safety and (2) help reorient Federal inspection to better address product,

process and plant risks. A regulatory program that imposes better manufacturing process control methods as a means to reduce pathogen contamination and control other hazards emphasizes the fact that industry is primarily responsible for product safety while the Government's role is oversight.

B. Factors Considered in Evaluating A Process Control Strategy

The process control regulatory strategy was evaluated using five factors for effectiveness. A processing control program is effective if it:

1. Controls production safety hazards;
2. Reduces foodborne illness;
3. Makes inspection more effective;
4. Increases consumer confidence; and
5. Provides the opportunity for increased productivity.

The following sections discuss these five effectiveness factors that have been applied to evaluate process control alternatives.

Controls Production Safety Hazards

Process control is a system for identifying food hazards and reducing or eliminating the risks they present. In operation, control points are established in a food production line where potential health hazards exist; management of these points has proven to be effective in reducing the probability that unsafe product will be produced. Ongoing records of each process control will enable plant managers and quality control personnel to spot trends that could lead to problems and devise a strategy that prevents them before they occur.

Detection by end product testing is not a viable alternative to process control because it only sorts good product from bad and does not address the root cause of unacceptable foods.

Additionally, keeping ''bad'' foods out of commerce through sorting end product is possible only when tests and standards for sampling are well established and it is practical only where the ''test'' is not expensive because sorting requires a huge number of samples for reliability.

Reduces Foodborne Illness

As industry improves its control over the safety aspects of meat and poultry production, foodborne illness will begin to decline. This is the principal non-negotiable goal for both USDA and industry.

The precise occurrence of human health problems attributed to pathogenic microorganisms or other potential foodborne hazards, such as chemical contaminants, animal drug residues, pesticides, extraneous materials, or other physical contaminants is not known. Foodborne illness is nevertheless recognized by scientists around the world as a significant public health problem and there is wide agreement that pathogenic microorganisms are the major cause of food-related disease. The cost of foodborne illness related to meat and poultry products alone is between $4.5–7.5 billion annually.

Makes Inspection More Effective

Currently, FSIS inspectors in meat and poultry plants perform random inspection tasks that generate independent data about a plant's production processes and environment. This activity produces ''snapshots'' of plant operations at that moment. In contrast, process control generates records of plant performance over time. These records and periodic verification inspections will enable FSIS inspectors to see how a plant operates at all times, i.e., whether and where processing problems have occurred, and if so, how they were addressed.

The availability of more and better processing data will establish trends that set benchmarks from which deviations can be more quickly and accurately assessed. USDA inspectors will be trained to spot these deviations and take action when needed to ensure plants bring a faulty process back into control. This type of Federal oversight is substantially more effective than a regulatory program that merely detects and condemns faulty end products. In the words of the National Advisory Committee on Microbiological Criteria for Foods, ''Controlling, monitoring, and verifying processing systems are more effective than relying upon end-product testing to assure a safe product.''

Increases Consumer Confidence

The number of foodborne illness outbreaks and incidents attributable to pathogens in meat or poultry raise questions about whether federal inspection is as effective as it should be. Highly visible public controversies about meat and poultry inspection indicate an erosion of public confidence in the safety of meat and poultry products. There are growing demands that USDA improve its regulation of pathogens. The process control regulatory strategy described in this paper is USDA's response to those demands.

Many outbreaks of foodborne illness have been determined to be caused by mishandling of meat and poultry products after federally-inspected processing. USDA believes that additional efforts to reduce pathogens during manufacturing will reduce these risks as well. This, coupled with the improved retail regulatory controls from state adoption and enforcement of the Food and Drug Administration's Food Code should reduce this cause of illness.

A significant portion of the meat and poultry industry does not take advantage of readily available methods to control its manufacturing processes. This is due in large part to the fact that meat and poultry processing industries are relatively easy to enter and are composed largely of small and medium-sized firms. Managers in these firms are frequently not as knowledgeable about safe production practices as they should be.

The Department has concluded that further regulation will bring industry standards up to what can practically be achieved in the manufacture of meat and poultry products through current scientific knowledge and available process control techniques. Raising the safety floor through regulations that mandate better process controls will demonstrate to the public that USDA and industry are making a concerted effort to reduce the risk of foodborne illness from meat and poultry.

The economic benefits of increased consumer confidence can be conceptually realized in the amount consumers would be willing to pay for safer food. This overall 'willingness to pay' is made up of several components. It reflects consumer desires to avoid foodborne illness and the expected medical and other costs associated with pathogens. In theory the total benefit associated with processing control regulations could be decomposed into two parts: first, the reduction in medical and other costs associated with pathogen-related illnesses (as discussed in a previous section), and the additional benefits which accrue to consumers not made ill but who may place a value on reduced risk of exposure to pathogens. At this time, the data are not available to make quantitative estimates of the consumer's willingness to pay.

Provides the Opportunity for Increased Productivity

Better process control is a sound and rational investment in the future of our nation's meat and poultry industry. USDA's process control strategy will educate industry management about the need and methodology for development of a consistent, preventive, problem-solving approach to safety hazards, which can be expanded to other business objectives such as product

quality and production efficiency. There is much evidence of how process control has improved worldwide industrial productivity in the past 40 years. This proposal will extend process control principles to parts of the meat and poultry industry that have not formerly used them.

Some important non-safety benefits that will accrue from industry use of better process control methods are:

- First, better production controls will result in more efficient processing operations overall with fewer product defects. Fewer defects mean less reworking, waste and give-away, resulting in increased yields and more profit opportunities.
- Second, better controls will significantly reduce the risk to processors that product with food safety defects will slip into commerce. Expensive and embarrassing product recalls can be entirely avoided with proper process controls.
- Third, better control of pathogens will impact all microorganisms, including those responsible for decomposition, resulting in quality improvements and longer shelf life for products.
- Fourth, better production controls improve plant employee productivity which improves profit opportunities.

C. Evaluation of Mandatory HACCP to Provide Process Control

Considering the five effectiveness factors of process control, the most effective means for ensuring that all industry uses adequate process control systems is a mandatory HACCP regulatory program. This alternative clearly meets all five criteria described above. In fact, a mandatory HACCP program was judged to be the only option that will effect adequate processing improvements in all establishments throughout the industry. Only through mandatory HACCP can pathogen risks be minimized to the fullest extent possible; thereby reducing foodborne illness to the maximum, improving effectiveness of inspection, increasing consumer confidence, and ensuring a more viable industry. No other alternative accomplishes as much in these five areas as mandatory HACCP.

In summary, FSIS has determined that:

- HACCP is a processing control strategy that has been scientifically proven effective in food manufacturing plants; and, therefore
- Mandating HACCP systems in all plants under USDA jurisdiction will protect the public from unreasonable risks due to meat and poultry consumption.

HACCP is widely recognized by scientific authorities such as the National Academy of Sciences and international organizations such as the Codex Alimentarius. It is used today by a number of plants in the food industry to produce consistently safe products. This approach has been supported for years by numerous groups that have studied USDA meat and poultry regulatory activities.

In 1983 FSIS asked the National Academy of Sciences to evaluate the scientific basis of its inspection system and recommend a modernization agenda. The resulting report, issued in 1985, was the first comprehensive evaluation of a scientific basis for inspection. The 1985 NAS report provided a blueprint for change: it recommended that FSIS focus on pathogenic microorganisms and require that *all* official establishments operate under a HACCP system to control pathogens and other safety hazards.

After urging the intensification of ''current efforts to control and eliminate contamination with micro-organisms that cause disease in humans,'' NAS encouraged USDA to ''move as vigorously as possible in the application of the HACCP concept to each and every step in plant operations of all types of enterprises involved in the production, processing, and storage of meat and poultry products.''

The General Accounting Office (GAO) has also identified needed improvements in USDA's present inspection system. In its reports and congressional testimony, and in numerous publications, GAO has endorsed HACCP as the most scientific system available to protect consumers from foodborne illness. This sentiment is most clearly expressed in a May 1994 report, ''Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry,'' in which GAO recommended development of a mandatory HACCP program that includes microbial testing guidelines. GAO urged USDA to assist meat and poultry plants in the development of their microbial testing programs by, among other things, disseminating information on the programs already in operation.

A third major proponent of HACCP is the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which was established in 1988 by the Secretary of Agriculture to advise and provide recommendations to the Secretaries of Agriculture and of Health and Human Services on developing microbiological criteria to assess food safety and wholesomeness. Since 1989 NACMCF has prepared a series of reports on the development and implementation of HACCP. As one of its first tasks, the Committee developed ''HACCP Principles for Food Production'' in November 1989. In this report, the Committee endorsed HACCP as a rational approach to ensure food safety and set forth principles to standardize the technique. In 1992, the Committee issued an updated guide, ''Hazard Analysis and Critical Control Point System.''

In 1993 NACMCF defined the roles of regulatory agencies and industry in implementing HACCP. ''The Role of Regulatory Agencies and Industry in HACCP'' proposed responsibilities for FDA, USDA, and other agencies and industry during various phases of HACCP implementation. Similar suggestions for program change have been voiced by consumers, industry, state and local government representatives, as well as other constituent groups. For example, consumers at recent public hearings and the HACCP Round Table supported implementation of mandatory HACCP throughout the meat and poultry industry.

The meat and poultry industry has itself provided broad support for HACCP as a means to control pathogens, emphasizing that HACCP-based food production, distribution, and preparation can do more to protect public health than any Federal inspection program. They have recommended that HACCP be used to anticipate microbiological hazards in food systems and to identify risks in new and traditional products. State departments of health and agriculture have also endorsed the HACCP approach.

D. Evaluation of Other Alternatives

FSIS examined six other approaches before determining that mandatory HACCP was the most effective means for industry to eliminate pathogens in meat and poultry:

1. Status quo;
2. Intensify present inspection;
3. Voluntary HACCP regulatory program;
4. Mandatory HACCP regulation with exemption for very small establishments;
5. Mandatory HACCP regulation only for ready-to-eat products; and
6. Modified HACCP—recording deviations and responses only.

These alternatives were assessed using the five effectiveness factors presented in the previous section. Since

FSIS's goal is to achieve the maximum pathogen reduction possible, and none is judged to be as effective as mandatory HACCP, the costs of these alternatives are not relevant. The following six sections summarize the appraisal of each alternative.

Status Quo

This option would essentially continue plant processing controls and Federal inspection as they are now. Good plants with adequate methods for managing process lines would probably remain under control. The Agency, under its present authority, cannot shift resources out of good plants so the situation of poor performing plants is unlikely to change. This situation raises immediate questions about the first factor—controls production safety hazards—being met. Experience has proven that Federal inspection cannot substitute for management in establishments which have difficulty producing safe product consistently. Also, inspection cannot be as effective in the current plant environment as in a process control plant environment.

Status quo does not target industry and inspection resources at preventing hazards in areas of highest risk which leads to the greatest reduction in foodborne illness (factor two). In addition, food safety experts, consumers, and other observers have told USDA they are not satisfied with pathogen control by organoleptic methods as practiced in the present plant program. Doing nothing new would perpetuate consumer doubts about the ability of Federal inspection to regulate pathogens which is counter to factor four. Consequently, the Department has concluded that business as usual is not an acceptable response to proven problems with pathogens associated with meat and poultry products. Agency public health responsibilities alone require that more positive actions be taken.

Intensify Present Inspection

As one alternative to the proposed mandatory HACCP regulation, FSIS could intensify its present inspection system i.e., focus new resources on suspected areas of risk in each plant. This approach would assign to FSIS responsibility for designing, testing and mandating by specific regulation, process control systems for all meat and poultry products with potential safety hazards. A major flaw with this approach is the burden of ensuring a safe product would be placed largely on FSIS instead of plant managers where it belongs. Plant management would have little motivation to become knowledgeable about process control or to implement process control systems.

Agency experience with mandating specific requirements has sometimes succeeded, where HACCP-like regulations have been successful in correcting food safety problems in certain ready-to-eat products. However, these controls largely consisted of lethal heat treatments applied during final product processing. This approach is obviously inappropriate for product that is marketed raw which is most frequently associated with meat and poultry foodborne illness.

Thus, intensified regular inspection fails to meet the primary criterion for process control, i.e., control production safety hazards at all stages of meat and poultry slaughter and processing. Related to this failing, inspection would be ineffective without all plants maintaining process control systems (factor three.) This option would require significant resource increases and results in more of the same type of Federal oversight which would be more costly to taxpayers without the payback of significant reductions in foodborne illness (factor two). With the burden of control and monitoring on USDA's inspection force rather than plant managers, industry performance would be unlikely to improve. Industry growth would be less certain which is counter to meeting factor five.

Voluntary HACCP Regulatory Program

A voluntary HACCP program would not provide reduction of pathogens uniformly across the processing spectrum (i.e., many in industry would choose not to participate) and therefore would not be sufficient to attain the necessary reduction in foodborne illness (factor two).

Voluntary HACCP would be implemented most frequently in plants with good processing controls already, while plants with unsophisticated controls would be less likely to participate. The explanation for this flaw is to be found in simple economics and, to a large degree, the attitudes of plant management. Plants with good processing controls now are most likely to adopt HACCP voluntarily because their management understands the linkage between how a product is handled during preparation and its finished quality and safety.

Conversely, plants without good processing controls today are much less likely to participate in a voluntary HACCP program. These plants are more often operated by management that lacks the knowledge or motivation to institute better processing controls. Nevertheless, it is precisely this group of low performing plants that FSIS must reach to attain its public health goal. Nothing short of a mandatory HACCP regulatory program will be effective in bringing processing improvements to these marginal performers.

The Agency's regulation permitting the use of voluntary Total Quality Control (TQC) Systems provides a useful analogy to how effective a voluntary HACCP program would be. TQC focuses on establishment responsibility for meeting or exceeding the standards set by FSIS for all operations that are conducted in a plant, including incoming raw materials, processing procedures, critical limits for product standards, and action limits for establishment quality control personnel. These systems operate under Agency oversight with an emphasis on timely and accurate record-keeping and the necessity for appropriate action to be taken by an establishment when a limit set forth in an approved system is met or exceeded. However, over the last 10 years the number of plants with active TQC Systems has declined from a high of around 500 (approximately 8% of all plants) to the present 351 participating plants (approximately 5% of all plants). USDA experience has shown that a voluntary approach to HACCP would provide little assurance that a major portion of meat and poultry products had been produced under controls designed to minimize food safety hazards.

Mandatory HACCP Regulation With Exemption for Small Establishments

Under this alternative, FSIS would mandate HACCP; but, provide an exemption for small establishments as was done with nutrition labeling. However, since major goals in implementing HACCP are to improve processing controls and plant performance across all of industry (factor one) as a means to achieve foodborne illness reductions (factor two), this option is inherently flawed by exemption of plants that perform the least process control. USDA inspection experience shows that some of the small establishments which would be exempted under this option have particular difficulties maintaining control over their processing system.

While it is true that small establishments produce a minimal amount of the total meat and poultry supply, they do produce a full range of products, including those most frequently associated with foodborne illness from the meat and poultry supply.

This option also fails on factor three—provide more effective inspection. Two

different inspection systems would be needed: one risk-based system to inspect HACCP plants with good processing controls; the other to provide resource intensive coverage for plants that largely do not. If the number of small plants continues to increase, more inspection resources would be required.

Mandatory HACCP Regulation Only for Ready-to-Eat Products

This option would mandate HACCP only for establishments that prepare ready-to-eat meat and poultry products, but not for plants that produce raw products. However, this decision would leave the public without adequate protection from pathogenic microorganisms clearly associated with product marketed in raw form. Very little reduction in the most frequent causes of foodborne illness (factor two) could be anticipated from this approach.

Government inspection costs would continue to increase to provide traditional resource-intensive inspection for slaughtering and allied processing plants that would not be subject to mandatory HACCP. Since most of the unsolved problems with pathogenic microorganisms are associated with raw products, not on those which would be the subject of this HACCP option, this is an especially inappropriate regulatory approach.

Modified HACCP—Only Recording Deviations and Responses

A final alternative considered would be to mandate HACCP, modified to eliminate the recordkeeping burden to the inspected industry, especially small establishments. Specifically, this option would modify the HACCP record-keeping principle so that instead of demanding continuous records at critical control points, companies would need to record only deviations from critical limits and the response to them. This would mean that HACCP-controlled operations would not generate continuous monitoring data to reflect the operation at critical control points, but would only record data when deviations occurred. This arrangement eliminates the continuous picture of plant operations which is the underpinning of factor three—make inspection more effective.

Such an approach would substantially reduce the paperwork burdens associated with mandatory HACCP as recommended by NACMCF and recognized by CODEX. However, it would also seriously compromise the usefulness of HACCP as a means to make inspection more effective and avoid program cost increases. Regulatory officials need to have a system which can be reviewed in its entirety, so that a comprehensive picture of the process is available, not just the truncated version which grows out of recording deviations.

IV. HACCP Benefits—Foodborne Illness

A. Incidence of Foodborne Illness in the United States

The safety of the meat and poultry supply has been widely discussed during the past few years. Precise data on the incidence of illness associated with meat and poultry or other food products are lacking. There is no mandatory reporting system for such illnesses and there is no complete national database on the occurrence of human health problems that might be attributed to pathogenic microorganisms or potential foodborne hazards, such as chemical contaminants, animal drug residues, pesticides, extraneous materials, or other physical contaminants. Foodborne illness is nevertheless recognized by scientists as a significant public health problem in the United States, and there is wide agreement among scientists that pathogenic microorganisms are the primary cause of foodborne illness. The following discussion focuses on pathogenic microorganisms.

Foodborne illness can strike individuals of all ages, sexes, nationalities and socioeconomic levels. People have been getting sick from foods throughout the ages; the reasons change but the problem persists. The most common types of foodborne illness typically appear as acute gastroenteritis with sudden onset of vomiting or diarrhea, or both, with accompanying abdominal pain. Some episodes include fever, prostration, shock, or neurological symptoms. The incubation period, i.e., the time between eating and onset of first symptom, as well as the type and duration of symptoms can vary from a few hours to several days, depending on the etiological agent, the infected individual's genetic predisposition and physical condition. In a percentage of the population—especially among children, the elderly, and immuno-compromised individuals—foodborne illness can be life-threatening.

Researchers estimate that between 6 and 33 million people, (between 3 and 14 percent of the population) become ill each year from pathogenic microorganisms in their food. An estimated 6,000 to 9,000 of these illnesses annually result in death. Other data show at least 18 million cases of diarrheal disease of foodborne origin occur in the United States annually; another several million persons may be affected by secondary person-to-person spread of infectious agents from cases caused by consumption of pathogen-contaminated food.

Foods contaminated with pathogenic microorganisms can lead to infection and illness in two major ways. The first is by direct consumption of the contaminated food under conditions that allow the survival of the pathogen or its toxin, such as when a meat or poultry product is consumed raw or undercooked. The second way contaminated product can lead to illness is through cross-contamination in the processing plant (e.g. cooked product), kitchen or other food-handling area, such as when the *Salmonella*-contaminated exterior of raw chicken contaminates a cutting board, countertop, or kitchen utensil, which then comes into contact with cooked product or foods consumed raw, such as salad. For some pathogens, such as *Salmonella,* more cases of illness result from cross-contamination than from direct consumption of undercooked product. Poor hygiene by infected food handlers, plant employees, etc, can also introduce pathogens which later cause illness.

Foodborne illness appears to have remained steady or increased slightly during the last decade. Possible increases in foodborne illness are variously attributed to changes in animal production procedures, automated processing, increased reliance on fast foods, greater use of prepackaged foods and microwave ovens, extended shelf-lives, more complex distribution systems, urbanization, public naivete about food manufacturing methods, and lack of knowledge about the hygienic precautions required at all stages of food handling, including preparation and serving. Other factors contributing to reported increases may include better surveillance, improved reporting, more sensitive diagnostic tests, emerging pathogens, and improved methods of detecting pathogens and chemical residues.

Data for evaluating trends and the most common causes of foodborne illness are compiled by the Centers for Disease Control and Prevention (CDC), based on reported ''outbreaks'' of illness, discussed below.

Estimates of the current foodborne disease burden in the United States are based on estimates of the annual incidence of disease. Incidence estimates are the annual estimates of the new cases of foodborne disease which occur each year. CDC compiles reports from State and local health authorities of foodborne illness outbreaks where

two or more persons have become ill from a common source. These reported cases are only a fraction of the actual annual incidence of foodborne disease cases for many reasons:

- Symptoms typical of several forms of foodborne illness include diarrhea, vomiting, abdominal pain, and physical weakness. These symptoms are also common to a wide variety of bacterial and viral infections not generally associated with food consumption. Consequently, many treated cases of foodborne illness are generically diagnosed as non-specific gastroenteritis or ''the flu'' and not identified as being caused by a specific foodborne pathogen.
- Most foodborne illness is transitory and self-limiting. People often become sick within a few hours after consumption of contaminated food, suffer acute symptoms, and recover spontaneously. These people are unlikely to seek medical attention, and will not become part of the reporting database.
- While some foodborne pathogens cause illness within a few hours of food consumption (*Staphylococcus aureus* and *Salmonella*), many common pathogens cause illness after a lag of several days (*E. coli* O157:H7 and *Campylobacter*) or weeks (*Listeria monocytogenes*). The longer the lag between consumption and illness, the less likely the connection to food will be made.
- Individual cases of foodborne illness are excluded from the CDC reporting system, except for botulism, toxic fish, mushrooms, and certain chemical poisonings where one case constitutes an outbreak.
- Around half of CDC's reported outbreaks and cases are never identified with a causative pathogen.
- CDC primarily relies upon voluntary reporting from State and local health agencies which, in turn, rely on hospitals, clinics, and individual health care professionals for information. All these institutions have resource limitations and different disease reporting requirements. For example, 12 States have no surveillance staff assigned to monitor foodborne diseases.

For the 4 foodborne pathogens of greatest concern, the case and severity estimates presented here are the ''best estimates'' of the actual incidence of foodborne disease associated with specific pathogens, rather than the fraction of cases actually reported to CDC. Many of the ''best estimates'' were developed by the landmark CDC study by Bennett, Holmberg, Rogers, and Solomon, published in 1987, which used CDC surveillance and outbreak data, published reports, and expert opinion to estimate the overall incidence and case-fatality ratio for all infectious and parasitic diseases, and identified 17 as foodborne pathogens. All the estimates of bacterial foodborne disease cases in Table 3 are based on CDC data to estimate actual cases of foodborne disease caused by each pathogen. (The estimated cases for the parasitic disease, congenital toxoplasmosis, are based on various reports in the medical literature.)

TABLE 3.—REFERENCE SOURCES OF DATA FOR SELECTED HUMAN PATHOGENS, 1993

Pathogen	Foodborne illness cases (#)	Source(s) for case estimates
Bacteria:		
Campylobacter jejuni or coli	1,375,000–1,750,000	Tauxe; Tauxe et al.
Clostridium perfringens	10,000	Bennett et al.
Escherichia coli O157:H7	8,000–16,000	AGA Conference.
Listeria monocytogenes	1,616–1,674	Roberts and Pinner; Schuchat.
Salmonella	732,000–3,660,000	Helmick et al.; Bennett et al.; Tauxe & Blake.
Staphylococcus aureus	1,513,000	Bennett et al.
Parasite:		
Toxoplasma gondii	2056	Roberts, Murrell, and Marks.

Sources: American Gastroenterological Association Consensus Conference on *E. coli* O157:H7, Washington, DC, July 11–13, 1994.

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Data collected by CDC also show food source for foodborne illness. Food products of all types, including beef, pork, turkey, chicken, bakery products, dairy products, eggs, finfish, shellfish, ice cream, mushrooms, fruits and vegetables, are associated with foodborne illness. Among foodborne illness outbreaks reported to CDC, the majority of those which can be identified are traced to pathogenic bacteria. The six target pathogens account for nearly all meat and poultry foodborne illness outbreaks and about 75% of total reported outbreaks caused by a bacterial agent.

B. Costs of Foodborne Illness

Table 4 shows the estimated cost of all foodborne illness to be approximately $5.6–9.4 billion in 1993.

Meat and poultry products are associated with approximately $4.5–7.5 billion and the remaining $1.1–1.9 billion is associated with non-meat and poultry sources.

TABLE 4.—Foodborne Illness Costs and HACCP Benefits, 1993

Food source	Foodborne illness	
	Costs billions)	Benefits (billions)
All Foods	$5.6–9.4	
Non-meat and Poultry	$1.1–1.9	
Meat and Poultry Only	$4.5–7.5	
Meat and Poultry Parasitic Pathogens	$2.7	
Meat and Poultry Bacterial Pathogens	$1.8–4.8	
USDA Target Bacterial Pathogens	$1.1–4.1	
Campylobacter jejuni/coli—.5–.8		
E. coli 0157:H7—.2–.5		
Listeria monocytogenes—.1–.2		
Salmonella—.3–2.6		
Reduction of USDA target pathogens attributed to HACCP (90%)	.....	.99–3.7

Source: Economic Research Service and Centers for Disease Control and Prevention.

The proposed HACCP system is designed to control all of the public health hazards identified in each meat and poultry establishment. FSIS regulation currently and under HACCP will address all public health hazards. Table 5 shows the bacterial pathogens largely responsible for meat and poultry illnesses.

The proposed near-term requirements and significant parts of HACCP will target pathogen reduction on carcasses and raw product, currently the least systematically controlled hazard. This is the most effective overall approach for reducing pathogen contamination. The benefits are calculated for the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli 0157:H7, Salmonella* and one environmental pathogen Listeria monocytogenes. The reduction of these pathogens to as near to zero as possible in meat and poultry during slaughter and processing would produce an estimated 90% reduction in the foodborne illness attributed to these microbial pathogens. The remaining 10% are due to causes not affected by the proposed regulations because contamination also occurs after product leaves the inspected plant. (The estimated reduction is based on the expert judgement of FSIS microbiologists.) This would result in a $.99–3.69 billion saving annually, as shown in Table 4.

Two other pathogens—*Clostridium perfringens* and *Staphylococcus aureus*—primarily enter meat and poultry foods in restaurants, other commercial kitchens and in homes. Consequently, the proposed regulatory program, which focuses on federally inspected processing, will not significantly affect the incidence of disease caused by these organisms. It is expected, however, that the FDA's Food Code will dramatically reduce the cause of illness attributable to retail practices upon its adoption and implementation. Our continued consumer education activities coupled with safe handling labels should significantly impact practices in the home.

The costs described in this section for foodborne illness costs are borne not only by those who become ill, but by their families, and employers; the food industries; and taxpayers. Costs to stricken individuals include medical bills, time lost from work, pain, and inconvenience. Food industry costs include product recalls, loss of plant production due to closings for cleanup, and higher premiums for product liability insurance. Perhaps most costly to industry in the long-term is loss of product reputation and reduced demand when an outbreak is traced back and publicized. These and other ''defensive'' industry costs of foodborne disease run in the millions of dollars annually and are, for the most part, entirely avoidable. Taxpayer costs include medical treatment for those who cannot afford it, including higher health insurance premiums and costs of public assistance to disabled individuals and their dependents.

Table 5.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED HUMAN PATHOGENS, 1993

Pathogen	Foodborne illness cases (#)	Foodborne* costs (bil. $)	Percent from meat/poultry (%)	Total costs* meat/poultry (bil. $)
Bacteria:				
Campylobacter jejuni or coli	1,375,000–1,750,000	0.6–1.0	75	0.5–0.8
Clostridium perfringens**	10,000	0.1	50	0.1
Escherichia coli O157:H7	8,000–16,000	0.2–0.6	75	0.2–0.5
Listeria monocytogenes	1,616–1,674	0.2–0.3	50	0.1–0.2
Salmonella	732,000–3,660,000	0.6–3.5	50–75	0.3–2.6
Staphylococcus aureus**	1,513,000	1.2	50	0.6
Subtotal	3,639,616–6,950,674	2.9–6.7	N/A	1.8–4.8
Parasite:				
Toxoplasma gondii	2,056	2.7	100	2.7

Table 5.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED HUMAN PATHOGENS, 1993—Continued

Pathogen	Foodborne illness cases (#)	Foodborne* costs (bil. $)	Percent from meat/ poultry (%)	Total costs* meat/poultry (bil. $)
Total	3,641,672–6,952,730	5.6–9.4	N/A	4.5–7.5

Source: Economic Research Service and Centers for Disease Control and Prevention, 1993.
*Column rounded to one decimal place.
**Roberts' rough approximation of costs in ''Human Illness Costs of Foodborne Bacteria'', *Amer. J. of Agricultural Economics,* vol. 71, no. 2 (May 1989) pp. 468–474 were updated to 1993 dollars using the Consumer Price Index (all items, annual average). Cost estimates for other pathogens are more detailed, see the following for a discussion of the methodology: listeriosis—Roberts, Tanya and Robert Pinner, ''Economic Impact of Disease Caused by *Listeria monocytogenes*'' in *Foodborne Listeriosis* ed. by A.J. Miller, J.L. Smith, and G.A. Somkuti. Elsevier Science: Amsterdam, The Netherlands, 1990, pp. 137–149, *E. coli* O157:H7—Roberts, T. and Marks, S., ''*E. coli* O157:H7 Ranks as the Fourth Most Costly Foodborne Disease,'' *FoodReview,* USDA/ERS, Sept-Dec 1993, pp. 51–59, salmonellosis—Roberts, Tanya, ''Salmonellosis Control: Estimated Economic Costs,'' *Poultry Science.* Vol. 67 (June 1988) pp. 936–943, campylobacteriosis—Morrison, Rosanna Mentzer, Tanya Roberts, and Lawrence Witucki, ''Irradiation of U.S. Poultry—Benefits, Costs, and Export Potential, *FoodReview,* Vol. 15, No. 3, October-December 1992, pp. 16–21, congenital toxoplasmosis—Roberts, T., K.D. Murrell, and S. Marks. 1944. ''Economic Losses Caused by Foodborne Parasitic Diseases,'' *Parasitology Today.* vol. 10, no. 11: 419–423; and Roberts, Tanya and J.K. Frenkel, ''Estimating Income Losses and Other Preventable Costs Caused by Congenital Toxoplasmosis in People in the United States,'' *J. of the Amer. Veterinary Medical Assoc.,* vol. 196, no. 2 (January 15, 1990) pages 249–256.
N/A indicates item is not-applicable.

Other taxpayer costs include public health sector expenses to operate a disease surveillance system and to investigate and eliminate disease outbreaks. Approximately $300 million is spent for this annually by the Federal public health sector. Government costs in the United States, Canada, and other countries, average about $200,000 per foodborne illness outbreak.

Cost Computation Methodology

The costs of foodborne disease associated with meat and poultry pathogens were estimated using a traditional ''cost of illness'' method which includes medical costs, productivity losses, and special educational or residential care associated with some chronic conditions. Disease frequencies reflect CDC's ''best estimate'' of the actual number of foodborne illness cases each year.

The present value of lifetime medical costs for those becoming ill in 1993 was estimated using nationwide databases, such as published Medicare reimbursement rates and per-capita expenditures on physicians' services from the Health Care Financing Administration, the National Center for Health Statistics' National Hospital Discharge Survey, the American Hospital Association's Hospital Statistics, or Blue Cross/Blue Shield charges. The average cost to community hospital per patient was used to compute hospitalization costs.

Productivity losses occur because workers are ill and miss work. These have been approximated by the Average Weekly Earnings for non supervisory production workers in private nonagricultural jobs, published by the Bureau of Labor Statistics (BLS) of the U.S. Department of Labor, plus estimated fringe benefits. For illness in subsequent years, a present value of the reduced stream of earnings is calculated. For deaths, Landefeld and Seskin's human capital/willingness to pay method was used. It combines elements of both methods to generate the present value of expected lifetime after-tax income and housekeeping services at a 3-percent real rate of return, adjusted for an annual 1-percent increase in labor productivity and a risk-aversion premium that increases the estimates by 60 percent.

These cost estimates are based on the annual incidence of disease, rather than the prevalence, to help us estimate *preventable* illness. Incidence estimates are the annual increase in cases and associated disease costs. Interventions today which prevent future costs will eliminate all the medical, productivity, and special care costs of prevented cases, and so represents one component of the overall economic benefit of disease prevention.

C. The Relationship Between Foodborne Illness and Consumer Knowledge and Behavior

The National Academy of Science's *Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS-C)* (1990) repeated the theme of numerous other studies, stating ''. . . the public expects the government to ensure zero risk of meat-borne disease through inspection. The [NAS] committee heard little evidence that the public is aware that some bacterial contamination of raw meat is inevitable and no mention of the crucial role of food handling, preparation, and serving methods in limiting foodborne diseases.'' The disturbing but real fact that consumers fail to make a connection between their food handling behavior and safe food recurs throughout the literature on the subject.

Behavioral research shows that food habits are the most difficult of all forms of human behavior to change. This finding is supported by research of consumer knowledge and practices, which indicate that a large portion of the U.S. population lacks basic food safety information and skills and engages in food handling and preparation practices that epidemiological studies have linked with a significant number of foodborne illness outbreaks. Moreover, little correlation exists between consumers' food safety knowledge and their food handling and preparation practices. Even people who characterize themselves as ''knowledgeable'' do not necessarily follow good food safety procedures. The CDC estimates that 20–30 percent of foodborne illness is due in part to consumer mishandling of food.

Available evidence concerning consumer behavior related to safe food handling and preparation supports the need for a comprehensive pathogen reduction effort. Food safety can best be assured by establishing a ''chain of responsibility,'' with each participant in the food system, from the producer all the way through to the consumer—understanding, accepting, and acting on its responsibility for food safety. While FSIS will pursue and support all possible means of consumer education and outreach, the Agency realizes that consumer education alone will not control pathogen-related foodborne illness. This is even more true today than ever before, as more people in our society are assuming responsibility for food handling and preparation in the home and elsewhere, without

experience in food preparation and knowledge of safe food handling and storage methods. These people include:

- Food service workers, many of whom receive inadequate training, are part-time and teenagers, who experience high-turnover;
- Men and women in the workplace, who have minimal time for food preparation and often little experience or interest in food preparation;
- Children, who are increasingly expected to shop and prepare their own meals;
- Immigrants, who might not be able to read food handling instructions, or whose cultural practices include eating raw or very rare meat and poultry products. Other vulnerable sectors of the population, more severely affected by foodborne illness, are also increasing in size;
- Immunocompromised persons (i.e., persons with diabetes, cancer, chronic intestinal diseases, organ transplants, and AIDS);
- Persons 65 years and older—a growing proportion of the population—who, due to the normal decline in immune response, are at increased risk.

In 1993, to increase awareness about pathogens, FSIS promulgated a regulation requiring safe handling labels on most raw meat and poultry products. The Agency's Meat and Poultry Hotline provides consumers with immediate responses to questions about food handling and safety. These steps are important but they are not a substitute for building into the food production and regulatory system measures to reduce to the maximum extent possible the presence of microbial pathogens in meat and poultry products purchased by U.S. consumers.

V. Costs Associated With HACCP

This section details the costs to the meat and poultry industry of the proposed measures to control pathogenic microorganisms and other biological, physical and chemical hazards. Unless otherwise stated, the figures used are three-year undiscounted costs. They have been estimated for:

- Four near-term initiatives that could be implemented shortly after promulgation of a final rule. These include the creation of Standard Operating Procedures (SOPs) for sanitation and three pathogen reduction and control interventions: antimicrobial treatment of carcasses, microbiological testing, and time and temperature requirements for all raw product received, held, and shipped by inspected establishments.
- The longer-term Hazard Analysis and Critical Control Point (HACCP) systems developed by establishments would be phased in over an approximate three-year period after the final rule is promulgated.

Total cost of the near-term initiatives and the three-year HACCP implementation is estimated at $733.5 million. This includes $552.8 million for federally inspected establishments and $180.7 million for State establishments. The costs for small establishments, which make up about a third of the total establishments, are estimated at $330.6 million, or just under 45 percent of the total. The Agency recognizes the problem these costs could present to small firms and has requested in the proposal public comments that will help it make appropriate adjustments to modify this burden.

A. Cost Analysis Procedures

In estimating the costs of the proposed rule, FSIS used data generated by various Agency operational and research components such as Total Quality Control (TQC), Partial Quality Control (PQC), and the various Baseline Microbiological Surveys. An especially important source was the cost information from the HACCP Pilot Program conducted from 1991 to 1993. The cost analysis also relied heavily on four of the Agency's main databases.

New databases were created by merging selected variables from the four FSIS databases and enhancing them with additional economic and financial data. The Enhanced Economic Analysis Database contains information on each of the slaughter and processing establishments active as of August 1994.

Described below as a prelude to the sections containing the estimated near-term and long-term costs are the assumptions, criteria, and other factors underlying or used in this cost analysis. Details of cost methodology and estimations are available in an appendix.

1. Number of Establishments

There are 6,186 Federal slaughter, processing, and combination (performing both slaughter and processing operations) establishments. An additional 2,893 establishments fall under State inspection. For some cost analysis purposes, combination establishments (performing both slaughter and processing) were counted as two separate plants.

2. Establishment Size

For its cost analysis, FSIS defines a small establishment as one with less than $2.5 million in annual sales. (This definition does not coincide with the Small Business Association definition for a small business.) Using the FSIS criterion, 42.2 percent of processing plants (Federal and State) and 16.8 percent of slaughter plants would be considered small establishments. A medium establishment is defined as one with annual sales of more than $2.5 million and less than $50 million. A large establishment is one whose sales are greater than $50 million per year.

State establishments are all considered to be small establishments. Since figures on these plants' sales volumes were not available, the size determination was based on amount of production, which was below the average for Federal establishments with sales less than $2.5 million. FSIS invites comments on the State classifications.

3. Process Categories

In keeping with the process control principles inherent in HACCP, FSIS identified 14 process categories (see Table 6 at the end of this section.) There is a separate category for each of the nine actual slaughter and processing processes and for each of the five species slaughtered. FSIS believes the 14 categories encompass all the products of the regulated industry. Every plant must develop a HACCP plan for each applicable category. The estimated costs for plan development are based on the total number of processes in all plants.

4. Implementation Schedule

FSIS plans that the final rule will become effective. The near-term initiatives would go into effect three months after it is published in the **Federal Register** and remain in effect in each plant until that plant's HACCP program begins (except for the sanitation SOP's, which will continue with HACCP). HACCP implementation would be phased in by process over three years, from date of final rule promulgation, with each process category assigned a slot in that time frame when its HACCP plan would be implemented. Small plants would have the option of implementing the plans for all their processes three years from promulgation instead of implementing plans for individual processes according to the time frame for medium and large plants.

5. Compliance

Some establishments may find that their present process(es) cannot consistently produce product that meets the specified interim target. This target, although a new ''measure'' of safety, is

based on levels currently achieved by many industry plants and is considered by the Agency to represent the current acceptable level of safety. An establishment whose product does not meet the target under the proposed requirements must, as it must do under current regulations, take action to adjust its process to produce product that meets this standard. The cost of taking this action is not considered a cost of the proposed requirement.

6. Equipment and Materials

The proposed rule does not make any existing equipment obsolete. (Some modification may be necessary, however, such as increasing cooling capacity for complying with the time-and-temperature requirements.) The proposal does require establishments to systematically monitor their processes. Costs of the necessary materials, such as thermometers and test kits, are estimated at $10 to $20 per establishment.

7. Wages

The hourly wage rates used in estimating costs are based on data from the Bureau of Labor Statistics and *Meat and Poultry Magazine*. They are $25.60 for a quality control manager, $18.13 for a quality control technician, and $12.87 for a laborer. They include a 33 percent overhead rate.

8. Cost Offsets

Because many establishments are currently operating or capable of operating quality control systems and programs, total costs are reduced to the extent that establishments already have the required plan development, monitoring, record keeping, and training.

9. TQC Overtime Costs

With the publication of the rule, TQC plants could lose their authority to produce and ship product after their normal shift production time. As a result, 287 active TQC establishments could begin to incur annual overtime charges.

B. Costs of the Near-term Initiatives

Costs associated with the four near-term initiatives can be thought of as pre-implementation HACCP costs. Since these interventions or similar controls will for the most part be incorporated into HACCP systems, their cost will reduce the overall cost of HACCP. Total cost of these initiatives is estimated at $358.9 million, including $266.7 for Federal establishments and $92.3 million for State establishments. The estimated cost to small establishments is $172.9 million. The four initiatives and their estimated costs are described below.

1. Sanitation Standard Operating Procedures

Federal plants—$81.1 million
State plants—21.0 million
Total—$102.1 million
Small establishments—$50.4 million

The SOPs would not add new sanitation standards but would require documentation of cleaning and sanitizing procedures for all equipment and facilities involved in the production of every product. This would serve as a basis for the plant's monitoring and the inspector's verification. An establishment's owner or manager would be required to detail in a written plan how the basic sanitation requirements would be met. Establishment employees would record results of the daily sanitation checks on a checklist, which would be made available to the inspector.

The amount of time to develop the plan would vary by establishment size, equipment, production capacity, and the process being performed. Plan development costs are one-time costs which would be incurred in the six months before the effective date of the regulation. They are estimated at $1.99 million for Federal establishments and $0.522 million for State establishments. Establishments now following a written sanitation program are not considered in the one-time or the recurring cost estimates.

Training establishment employees in the requirements of the SOP intervention program would represent another one-time cost incurred in the six months before the regulation takes effect. The training cost for Federal establishments is estimated at $1.1 million and for State establishments $0.251 million.

Recurring SOP costs would involve recordkeeping. Annual record keeping costs are estimated at $19.5 million for Federal establishments and $5.1 for State establishments.

2. Antimicrobial Treatments

Federal plants—$58.7 million
State plants—0.6 million
Total—$59.4 million
Small establishments—$2.7 million

Slaughter establishments would be required for the first time to provide antimicrobial treatments before the carcasses enter the chiller or cooler. Costs are reduced by the number of establishments already meeting these requirements. In estimating the resulting costs, it is assumed that the establishments would use the most cost-effective treatment. For meat establishments the cost analysis is based on the hot water system, at a cost of $.08 per carcass. For poultry establishments it is based on a hypochlorination system at $.0125 per carcass.

3. Time and Temperature Requirements

Federal plants—$26.5 million
State plants—22.9 million
Total—$49.4 million
Small establishments—$28.8 million

These requirements are already in effect for poultry plants, so would affect only the meat industry. An establishment would be required to maintain the cooled carcass and raw meat at the specified temperature throughout handling, holding, and shipping to other official establishments. Costs are reduced by the number of meat establishments already meeting these requirements. First-year costs for Federal establishments are estimated at $13.7 million, which covers developing a plan, training employees, upgrading cooling equipment, and keeping records. For State establishments the estimate is $18.9 million.

4. Microbiological Testing

Federal plants—$100.3 million
State plants—47.8 million
Total—$148.1 million
Small establishments—$91.1 million

FSIS would mandate testing and reporting procedures to determine the pathogen incidence rate for each process at each establishment that slaughters livestock or poultry or produces raw, ground meat or poultry products. One-time costs for plan development and employee training are estimated at $6.7 million.

Specimens would be collected once a day at the end of the production process and tested for the presence of the target organism (*Salmonella*) in the establishment's own laboratory or in a commercial/contract laboratory. The sample collection and analysis cost in the first year after promulgation of the rule is estimated at $67.5 million. This includes $46.4 for Federal establishments and $21.1 million for State establishments. The cost for small establishments represents 59 percent of the total, or $39.8 million.

First-year costs for record keeping are estimated at $2.4 million. Large establishments account for only about 10 percent of this total, since most of them are already performing quality control functions which require continuous records.

C. Costs of the Long-term HACCP Intervention

Federal plants—$279.7 million
State plants—88.5 million
Total—$368.2 million
Small establishments—$157.6 million

The near-term initiatives are a prelude to the types of activities that are required under a HACCP process control system. The HACCP costs above, which represent the full 36-month implementation period, include continuing components of the previous initiatives and the new costs listed below:

1. Industry HACCP Training

FSIS would require that each establishment have at least one person complete a course of at least three days in the application of HACCP principles. The total estimated cost of $27.9 million was calculated by multiplying a per-course cost of $2,514 (for tuition, travel expenses, and labor replacement) by the number of Federal and State establishments now lacking someone with the necessary training (assumed to be 95 percent of establishments).

2. Plan Development

FSIS would require each inspected establishment to have and implement a HACCP plan that is specific to each kind of meat or poultry process performed in the establishment. The Agency is aware that the requirement may be especially burdensome to small establishments producing small amounts of a variety of products.

In estimating the cost of the plans, FSIS considered the difficulty of writing a plan for each of the 14 HACCP processes that encompass all meat and poultry products. The cost for developing a plan ranges from $2,000 to $15,000 according to the degree of difficulty and its order of development. The overhead costs of developing the plant's first plan do not appear again for its subsequent plans.

Total plan development costs are estimated at $42.9 million: $30.7 million for Federal establishments and $12.2 million for State establishments. (In the absence of production information for State establishments, it was assumed that each will have 1.5 plans.) The total for small establishments is $21.6 million.

3. Aseptic Training

Plants not covered by the near-term microbiological testing requirement and that do not have their own quality control laboratory would have to train an employee to collect specimens for analysis. Estimated costs are $1.5 million for Federal plants and $.6 million for State plants. The total for small establishments is $1.5 million. (This cost is related to product testing. See item 4 below.)

4. Product Testing

The pre-HACCP product testing in slaughter plants and plants producing raw, ground product would continue under HACCP as described above under short-term initiatives. In addition, the Agency intends to require product testing in the processing plants not covered by the short-term requirement. Although the precise nature of this testing is not yet known, the Agency expects that in every establishment, at least one sample a day would have to be taken for each process. This would amount to nearly six million samples a year, at an estimated annual cost of $149.8 million. Although this testing requirement is not included in the proposed rule, it is discussed in the preamble and is included in the proposed costs in order to give a realistic estimate of the ultimate costs of the effort that is being initiated by this proposal.

5. Recordkeeping

A fundamental HACCP principle calls for recording and reviewing observations at critical points in the manufacturing process on an ongoing basis. The cost of recording this information is expected to total $47.9 million annually: $41.7 million for Federal establishments and $6.3 million for State establishments. The recording costs for small establishments are estimated at $11.9 million.

The cost of reviewing the records generated is expected to total $28.0 million annually: $24.5 million for Federal establishments; $3.5 for State establishments. The annual reviewing cost for small establishments is estimated at $6.7 million.

The annual cost of maintaining (storing) HACCP records as required would be $671,813: $575,852 for Federal establishments; $95,961 for State establishments.

6. FSIS HACCP Training

FSIS would provide employees with awareness training and HACCP inspection activity training. The estimated cost is $416,880.

D. Estimated Costs Per Plant

The following charts show the estimated costs for the near-term initiatives and for HACCP that would be incurred by various types of plants. The following steps can be followed to estimate, on the basis of FSIS estimates of cost, how much a particular establishment could expect to spend on one-time and recurring costs during the implementation period:

1. Determine the establishment's size (small, medium, or large) according to its annual sales volume, using the following criteria:

Small=less than $2.5 million sales
Medium=$2.5–$50 million sales
Large=over $50 million sales

2. Using the table for that size plant, find the column that describes its function (meat slaughter, poultry slaughter, or processing). Note that each type of operation is subdivided into two groups: those with and those without their own quality control laboratory. Plants with a laboratory will not have to spend as much in some cost categories. On the table for small plants, it is assumed that none have their own laboratory. On the table for large plants, it is assumed that all processing but not all slaughter plants have their own laboratory.

3. In meat slaughter plants, the HACCP costs for plan development and record keeping are per process, with each species counted as a separate process. For meat plants slaughtering more than one species, both costs must be multiplied by the number of species.

In poultry slaughter plants, only the HACCP cost for record keeping should be multiplied by the number of species slaughtered (chicken, turkey, and/or duck).

4. In processing plants, the HACCP costs for plan development and record keeping vary from process to process according to whether the process—and thus its HACCP plan—is easy, moderate, or difficult. To calculate a plant's total HACCP plan development and record keeping costs, perform these steps:

- For each process, use Table 6 to determine its degree of difficulty, and then, again using the relevant plant-size chart, find the plan development cost and the record keeping cost for that process. Write them down.
- Add all the plan development costs.
- Add all the record keeping costs.

Use the two sums instead of the table's per-process costs when the plant's total HACCP costs are calculated.

5. Under near-term interventions, note that modifying a cooler to comply with time-and-temperature requirements would cost an estimated $6,000. Any plant needing such modification should add $6,000 to the near-term interventions subtotal.

TABLE 6.—DEGREE OF DIFFICULTY FOR DEVELOPING A HACCP PLAN

Plan No.	HACCP process	Degree of difficulty
1	Raw: Ground	Easy.
2	Raw Other: Inclusive	Easy.
3	Thermally processed	Difficult.
4	All other shelf stable: not heat treated	Difficult.
5	Fully cooked: not shelf stable	Moderate.
6	Shelf stable: heat treated, other	Moderate.
7	Non-shelf stable: heat treated, not fully cooked	Moderate.
8	Non-shelf stable: with secondary inhibitors	Moderate.
9–14	Slaughter	Easy.

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TABLE 7. NEAR-TERM INTERVENTIONS AND HACCP COSTS FOR A SMALL PLANT*

INTERVENTION	FACTOR TO MULTIPLY BY	MEAT SLAUGHTER		POULTRY SLAUGHTER		PROCESSING**	
		QC LAB	NO LAB	QC LAB	NO LAB	QC LAB	NO LAB
NEAR-TERM INTERVENTION							
SANITATION		NA	$1,429	NA	$1,429	NA	$1,429
ANTIMICROBIAL TREATMENT PER HEAD * AVG. HEAD SLAUGHTERED***		NA	$590	NA	$37,894	NA	NA
TIME AND TEMPERATURE		NA	$762	NA	$762	NA	$762
T/T COOLER MODIFI. NEEDED = $6,000	YES/NO	NA		NA		NA	
MICRO. TEST. PLAN DEVELOPMENT****		NA	$512	NA	$512	NA	$512
MICRO. TESTING SAMPLE FOR 260 DAYS****	NUMBER OF SPECIIES/PROCESS	NA	$8,811	NA	$9,078	NA	$8,811
NEAR-TERM INTERVENTION COSTS		NA	$12,104	NA	$49,675	NA	$11,514
HACCP							
HACCP TRAINING		NA	$2,514	NA	$2,514	NA	$2,514
ASEPTIC TRAINING*****		NA	$403	NA	$403	NA	$403
MICRO. TESTING SAMPLE FOR 260 DAYS****	NUMBER OF SPECIIES/PROCESS	NA	$8,533	NA	$8,800	NA	$8,533

HACCP PLAN SPECFIC COSTS BY PLAN DEGREE OF DIFFICULTY		MEAT SLAUGHTER EASY PROCESS (5 CCPs)		POULTRY SLAUGHTER EASY PROCESS (5 CCPs)		PROCESSING** EASY PROCESS (6 CCPs)		MODERATE PROCESS (8 CCPs)		DIFFICULT PROCESS (10 CCPs)	
PLAN DEVELOPMENT	NUMBER OF SPECIIES/PROCESS	NA	$2,000	NA	$2,000	NA	$2,000	NA	$4,000	NA	$6,250
RECORD KEEPING	NUMBER OF SPECIIES/PROCESS	NA	$2,195	NA	$2,242	NA	$2,629	NA	$3,498	NA	$4,366
HACCP COSTS		NA	$15,645	NA	$15,959	NA	$16,079	NA	$18,948	NA	$22,066
TOTAL COSTS		NA	$27,749	NA	$65,634	NA	$27,593	NA	$30,462	NA	$33,580

* SIZE BY 1993 SALES VOLUME: SMALL = < $2.5 MILLION, MEDIUM = < $50 MILLION, LARGE = > $50 MILLION.

** SEE HACCP PROCESS DEFINITIONS AT TABLE 6.

*** PER CARCASS COSTS ARE $0.08 PER CARCASS AND $0.0125 PER POULTRY CARCASS.

**** NEAR-TERM INTERVENTION IS FOR ALL SLAUGHTER ESTABLISHMENTS AND RAW GROUND MEAT AND POULTRY PROCESSING.

***** DOES NOT PERTAIN TO SLAUGHTER OR RAW GROUND MEAT AND POULTRY PRODUCT PROCESSES.

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TABLE 8. NEAR-TERM INTERVENTIONS AND HACCP COSTS FOR A MEDIUM PLANT*

INTERVENTION	FACTOR TO MULTIPY BY	MEAT SLAUGHTER		POULTRY SLAUGHTER		PROCESSING**	
		QC LAB	NO LAB	QC LAB	NO LAB	QC LAB	NO LAB
NEAR-TERM INTERVENTION							
SANITATION		$2,619	$2,619	$2,619	$2,619	$2,619	$2,619
ANTIMICROBIAL TREATMENT PER HEAD * AVG. HEAD SLAUGHTERED***		$1,869	$1,869	$126,269	$126,269	NA	NA
TIME AND TEMPERATURE		$2,091	$2,091	$2,091	$2,091	$2,091	$2,091
T/T COOLER MODIFI. NEEDED = $6,000	YES/NO						
MICRO. TEST. PLAN DEVELOPMENT ****		$256	$512	$256	$512	$256	$512
MICRO. TESTING SAMPLE FOR 260 DAYS****	NUMBER OF SPECIES/PROCESSES	$5,459	$8,811	$5,836	$9,078	$5,459	$8,811
NEAR-TERM INTERVENTION COSTS		$12,294	$15,902	$137,071	$140,569	$10,425	$14,033
HACCP							
HACCP TRAINING		$2,154	$2,154	$2,154	$2,154	$2,154	$2,154
ASEPTIC TRAINING*****		NA	$403	NA	$403	NA	$403
MICRO. TESTING SAMPLE FOR 260 DAYS	NUMBER OF SPECIES/PROCESSES	$5,069	$8,533	$5,446	$8,800	$5,069	$8,533

HACCP PLAN SPECFIC COSTS BY PLAN DEGREE OF DIFFICULTY	FACTOR TO MULTIPY BY	MEAT SLAUGHTER EASY PROCESS (5 CCPs)		POULTRY SLAUGHTER EASY PROCESS (5 CCPs)		PROCESSING** EASY PROCESS (6 CCPs)		MODERATE PROCESS (8 CCPs)		DIFFICULT PROCESS (10 CCPs)	
PLAN DEVELOPMENT	NUMBER OF SPECIES/PROCESSES	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$4,000	$4,000	$6,250	$6,250
RECORD KEEPING	NUMBER OF SPECIES/PROCESSES	$2,242	$2,242	$2,242	$2,242	$2,676	$2,676	$3,521	$3,521	$4,413	$4,413
HACCP COSTS		$11,465	$15,332	$11,842	$15,599	$11,899	$15,766	$14,744	$18,611	$17,886	$21,753
TOTAL COSTS		$23,759	$31,234	$148,913	$156,168	$22,324	$29,799	$25,169	$32,644	$28,311	$35,786

** SIZE BY 1993 SALES VOLUME: SMALL = < $2.5 MILLION, MEDIUM = < $50 MILLION, LARGE = > $50 MILLION.

** SEE HACCP PROCESS DEFINITIONS AT TABLE 6.

*** PER CARCASS COSTS ARE $0.08 PER MEAT CARCASS AND $0.0125 PER POULTRY CARCASS.

**** NEAR-TERM INTERVENTION IS FOR ALL SLAUGHTER ESTABLISHMENTS AND RAW GROUND MEAT AND POULTRY PROCESSING.

***** DOES NOT PERTAIN TO SLAUGHTER OR RAW GROUND MEAT AND POULTRY PRODUCT PROCESSES.

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TABLE 9. NEAR-TERM INTERVENTIONS AND HACCP COSTS FOR A LARGE PLANT*

INTERVENTION	FACTOR TO MULTIPLY BY	MEAT SLAUGHTER		POULTRY SLAUGHTER		PROCESSING**	
		QC LAB	NO LAB	QC LAB	NO LAB	QC LAB	NO LAB
NEAR-TERM INTERVENTION							
SANITATION		$5,115	$5,115	$5,115	$5,115	$5,115	NA
ANTIMICROBIAL TREATMENT PER HEAD * AVG. HEAD SLAUGHTERED***		$62,146	$62,146	$427,980	$427,980	NA	NA
TIME AND TEMPERATURE		$3,791	$3,791	$3,791	$3,791	$3,791	NA
T/T COOLER MODIFI. NEEDED = $6,000	YES/NO						
MICRO. TEST. PLAN DEVELOPMENT****		$256	$512	$256	$512	$256	NA
MICRO. TESTING SAMPLE FOR 260 DAYS	NUMBER OF SPECIES/PROCESSES	$5,459	$8,811	$5,836	$9,078	$5,459	NA
NEAR-TERM INTERVENTION COSTS		**$76,767**	**$80,375**	**$442,978**	**$446,476**	**$14,621**	**NA**
HACCP							
HACCP TRAINING		$2,514	$2,514	$2,514	$2,514	$2,514	NA
ASEPTIC TRAINING*****		NA	$403	NA	$403	NA	NA
MICRO. TESTING SAMPLE FOR 260 DAYS	NUMBER OF SPECIES/PROCESSES	$5,069	$8,533	$5,446	$8,800	$5,069	NA

HACCP PLAN SPECFIC COSTS BY PLAN DEGREE OF DIFFICULTY		MEAT SLAUGHTER EASY PROCESS (5 CCPs)		POULTRY SLAUGHTER EASY PROCESS (5 CCPs)		PROCESSING** EASY PROCESS (6 CCPs)		MODERATE PROCESS (8 CCPS)		DIFFICULT PROCESS (10 CCPs)	
PLAN DEVELOPMENT	NUMBER OF SPECIES/PROCESSES	$2,000	$2,000	$2,000	$2,000	$2,000	NA	$4,000	NA	$6,250	NA
RECORD KEEPING	NUMBER OF SPECIES/PROCESSES	$2,242	$2,242	$2,242	$2,242	$2,676	NA	$3,521	NA	$4,413	NA
HACCP COSTS		**$11,825**	**$15,692**	**$12,202**	**$15,959**	**$12,259**	**NA**	**$15,104**	**NA**	**$18,246**	**NA**
TOTAL COSTS		**$ 88,59**	**$96,067**	**$455,180**	**$462,435**	**$26,880**	**NA**	**$29,725**	**NA**	**$32,867**	**NA**

* SIZE BY 1993 SALES VOLUME: SMALL = < $2.5 MILLION, MEDIUM = < $50 MILLION, LARGE = > $50 MILLION.

** SEE HACCP PROCESS DEFINITIONS AT TABLE 6.

*** PER CARCASS COSTS ARE $0.08 PER MEAT CARCASS AND $0.0125 PER POULTRY CARCASS.

**** NEAR-TERM INTERVENTION IS FOR ALL SLAUGHTER ESTABLISHMENTS AND RAW GROUND MEAT AND POULTRY PROCESSING ONLY.

***** DOES NOT PERTAIN TO SLAUGHTER OR RAW GROUND MEAT AND POULTRY PRODUCT PROCESSES.

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